### 424 R&R and PHS-398 Specific Table Of Contents

<table>
<thead>
<tr>
<th>Section</th>
<th>Page Numbers</th>
</tr>
</thead>
<tbody>
<tr>
<td>SF 424 R&amp;R Face Page</td>
<td>1</td>
</tr>
<tr>
<td>Table of Contents</td>
<td>3</td>
</tr>
<tr>
<td>Performance Sites</td>
<td>5</td>
</tr>
<tr>
<td>Research &amp; Related Other Project Information</td>
<td>7</td>
</tr>
<tr>
<td>Project Summary/Abstract (Description)</td>
<td>8</td>
</tr>
<tr>
<td>Public Health Relevance Statement (Narrative attachment)</td>
<td>9</td>
</tr>
<tr>
<td>Bibliography &amp; References Cited</td>
<td>10</td>
</tr>
<tr>
<td>Facilities &amp; Other Resources</td>
<td>15</td>
</tr>
<tr>
<td>Equipment</td>
<td>20</td>
</tr>
<tr>
<td>Other Attachments</td>
<td>21</td>
</tr>
<tr>
<td>List of references</td>
<td>21</td>
</tr>
<tr>
<td>Research &amp; Related Senior/Key Person</td>
<td>22</td>
</tr>
<tr>
<td>Biographical Sketches for each listed Senior/Key Person</td>
<td>25</td>
</tr>
<tr>
<td>Research &amp; Related Budget - Year 1</td>
<td>48</td>
</tr>
<tr>
<td>Research &amp; Related Budget - Year 2</td>
<td>51</td>
</tr>
<tr>
<td>Research &amp; Related Budget - Year 3</td>
<td>54</td>
</tr>
<tr>
<td>Research &amp; Related Budget - Year 4</td>
<td>57</td>
</tr>
<tr>
<td>Research &amp; Related Budget - Year 5</td>
<td>60</td>
</tr>
<tr>
<td>Budget Justification</td>
<td>63</td>
</tr>
<tr>
<td>Research &amp; Related Budget - Cumulative Budget</td>
<td>65</td>
</tr>
<tr>
<td>PHS 398 Specific Cover Page Supplement</td>
<td>66</td>
</tr>
<tr>
<td>PHS 398 Checklist</td>
<td>68</td>
</tr>
<tr>
<td>PHS 398 Career Development Award Supplemental Form</td>
<td>70</td>
</tr>
<tr>
<td>Introduction</td>
<td>72</td>
</tr>
<tr>
<td>Candidates Background</td>
<td>73</td>
</tr>
<tr>
<td>Career Goals and Objectives</td>
<td>75</td>
</tr>
<tr>
<td>Development Activities During Award Period</td>
<td>77</td>
</tr>
<tr>
<td>Training in the Responsible Conduct of Research</td>
<td>79</td>
</tr>
<tr>
<td>Statements by Mentor, Co-Mentors, Consultants, Contributors</td>
<td>80</td>
</tr>
<tr>
<td>Institutional Environment</td>
<td>85</td>
</tr>
<tr>
<td>Institutional Commitment to Career Development</td>
<td>87</td>
</tr>
<tr>
<td>Specific Aims</td>
<td>88</td>
</tr>
<tr>
<td>Research Strategy</td>
<td>89</td>
</tr>
<tr>
<td>Protection of Human Subjects</td>
<td>97</td>
</tr>
<tr>
<td>Women &amp; Minorities</td>
<td>103</td>
</tr>
<tr>
<td>Planned Enrollment Table</td>
<td>104</td>
</tr>
</tbody>
</table>
Children

Consortium/Contractual

Resource Sharing Plan
PROJECT SUMMARY

Childhood overweight is an important public-health problem in the US. Current estimates indicate that one in three children is overweight. Over half of overweight 5-10 year-old children have at least one cardiovascular disease risk factor, and overweight increases the lifetime risk of cardiovascular morbidity and premature death, but these risks are reduced in overweight children who attain a normal weight. During well-child visits, pediatricians have an opportunity to address weight and weight-management. Little is known, however, about clinical practice elements and pediatrician-patient communication strategies associated with weight improvement in overweight children. The overall objective of the proposed project is to identify specific clinical practice elements and pediatrician-patient communication strategies during well-child visits that predict improvement in relative weight among overweight children. This will be accomplished through three specific aims, which are to 1) identify specific clinical practice elements in pediatric primary care that predict improvement in weight status; 2) determine communication strategies that predict improvement in weight status; and 3) develop and test the feasibility and acceptability of a pilot intervention to improve pediatricians' communication and use of specific clinical practice elements when addressing weight and weight management during primary-care visits with overweight children. For Aim 1, electronic medical records (EMR) will be analyzed to determine clinical practice elements (such as lab assessments and follow-up interval) associated with improvement in weight status at one year follow-up. For Aim 2, Roter Interaction Analysis of video-recorded well-child visits will be used to analyze pediatrician-patient communication regarding weight and weight-management (including assessment and counseling regarding overweight status, and communication dynamics, including patient-centeredness), and children will be followed, by tracking interval visits, weights/heights, and referrals using the EMR, over one year. Findings from Aims 1 and 2 will be used in Aim 3 to develop and test the feasibility and acceptability of a pilot intervention aimed at improving pediatricians' observed and self-reported competence in using specific clinical practice elements and effective communication when addressing overweight during primary-care visits, compared with a control group of standard practice. The proposed Career Development Award addresses how to improve overweight/obesity management in primary care, a research priority of an NHLBI Working Group convened to set future research priorities in childhood obesity prevention and treatment. The exceptional resources and institutional support at UT Southwestern, outstanding multi-disciplinary mentorship team, and proposed career development activities will allow the candidate to achieve her long-term goal of becoming an independent investigator and nationally recognized expert on primary-care based interventions that are effective in improving childhood overweight and obesity.
There is an urgent need to identify strategies that lead to successful weight improvement for overweight children: although overweight increases the lifetime risk of heart disease and early death, these risks are reduced in overweight children who attain a healthy weight by adulthood. The goal of the proposed research is to identify specific clinical practice elements and communication strategies in pediatric primary care that pediatricians already are using which help children attain healthier relative weights, and pilot an intervention to translate study findings into clinical practice. Achievement of the study aims has the potential to be a significant contribution to promoting weight improvement for overweight children, as the proposed research could lead to the development of an effective intervention to improve pediatricians' communication and use of specific clinical practice elements when addressing weight and weight management for overweight children in primary care.
FACILITIES AND OTHER RESOURCES

University of Texas Southwestern Medical Center: The Division of General Pediatrics at UT Southwestern, which is directed by [redacted] primary mentor, Dr. Glenn Flores, has all of the necessary resources, staff, and capacity to successfully conduct and complete the proposed case-control, observational, and survey studies, and pilot intervention to identify clinical practice elements and communication content that predict improvement in child overweight. In this section, we describe the office space, staff, and other resources available for the proposed career development award studies.

Office Space: The Division of General Pediatrics consists of 2,322 square feet of office space, including 11 workstations. Each workstation is equipped with a high-speed networked desktop computer, a printer or a network connection to a shared printer, and a telephone. A combination fax machine/photocopy is available to the Division, as well as two high-speed copiers in close proximity that serve the Department of Pediatrics. Dr. Turer has her own 280 square-foot office with a networked computer, printer, and telephone.

Staff: The current staff in the Division of General Pediatrics comprise an experienced, dedicated team of research personnel. Statistical analyses and data management are capably handled by the Division's full-time statistician, who has a B.A. and M.A. in Economics, an M.S. in Epidemiology and Biostatistics, a Ph.D. in Health Economics, eight years of research experience with data analysis on healthcare data, expertise in multi-level modeling using SAS, structural equation modeling using STATA, as well as expertise with SPSS, Microsoft Access, and Microsoft Excel. Administrative needs are capably handled by one full-time Administrative Associate and one full-time Senior Administrative Assistant. The Division's full-time Program Coordinator has extensive experience on and experience with intervention projects, working with diverse populations, and managing teams of research assistants and technicians; she has collaborated with Dr. Flores for two years, and has collaborated with the PI for the past year.

Other Resources:

Children's Medical Center Primary Care Continuity Clinic (Academic Clinic): Children's Medical Center's (CMC) Continuity of Care Clinic will serve as one of three clinic sites for patient recruitment for the Aims 1 and 2 studies. The practice priority of the CMC Clinics is to improve the health and well-being of children through excellence in pediatric clinical care and advocacy regarding improving access to and quality of care for underserved populations of children. This academic, hospital-based clinic, which is part of the UTSW Division of General Pediatrics, uses an EPIC-based electronic medical record (EMR) system, and is staffed by pediatric residents supervised by attending physicians. Only second and third-year residents will be eligible (N=28). As described in the Research Strategy, the reason for the focus on senior residents is that they see an individual patient for every appointment, whereas the attending physician can be different for each appointment. Twenty-eight residents follow patients in the CMC Continuity Clinic, and (of the classes that would be recruited) over one-third are minority pediatricians (three Latino, three African-American, and four Asian). The practice primarily cares for children covered by Medicaid, CHIP, and the uninsured; most patients are racial/ethnic minorities—the two largest being Latino and African-American. There are 13 patient exam rooms, including a large exam room that previously has been used for videorecording pediatrician-patient interactions. Dr. Nancy Kelly is the Medical Director of the CMC Continuity Clinic and will serve as [redacted] liaison to the Clinic's administrative staff, physicians, and patients to ensure successful pediatrician and patient recruitment, and data collection (see Letter of Support from Dr. Nancy Kelly).

Los Barrios Unidos Community Clinic: Los Barrios Unidos Community Clinic (LBUCC) is a federally-qualified community health center in the Dallas County area that provides comprehensive primary care services. The practice priority of LBUCC is "to welcome all and improve quality of life through excellence in accessible, affordable healthcare." In 1972, the residents of several West Dallas neighborhoods united to open a community clinic in a portable building to serve a population disenfranchised from the economic and social services of the city due primarily to language and cultural differences. LBUCC provides primary-care services that include pediatrics, prenatal care, adult care, mental health care, dental care for children, WIC services, and other supportive services. LBUCC has been fully accredited by The Joint Commission since 1998. To achieve this accreditation, clinic outcomes are systematically monitored and licensed physicians, dentists, and
nurses are formally credentialled and granted clinical privileges. To track outcomes, Los Barrios uses a NextGen-based EMR.

Ninety-three percent of LBUC's 26,000 patients are Latino and 70% are uninsured. Families receiving LBUC's services may pay on a sliding fee scale based on federal poverty level guidelines that are updated every year. The Clinic also accepts Medicaid, CHIP, and Medicare, and no one is turned away for the inability to pay. Nearly 30 clinicians provide 69,000 patient visits each year. All six of LBUC's full-time pediatricians are fluent in Spanish, and half are from racial/ethnic minorities (Latino, African-American, Filipino). Patients are drawn from all parts of Dallas County.

LBUC collaborates closely with the UTSW Division of General Pediatrics; two UTSW faculty see patients and precept residents at LBUC (in an adjoining building). For the Aim 2 study, however, we will only recruit non-resident, full-time staff pediatricians, because LBUC was chosen to represent community-based clinics, while CMC will represent academic, hospital-based clinics. LBUC collaborated with Dr. Briner on her preliminary communication study, and will continue to collaborate closely with her on the proposed projects, with the permission and guidance of the clinic's medical director, Dr. Susan Briner. Dr. Briner will oversee the use of LBUC EMR content, and facilitate interactions with LBUC pediatricians and patients to ensure successful recruitment and data collection (see Letter of Support from Dr. Susan Briner).

**Pediatric Associates of Dallas (Private Clinic):** Pediatric Associates of Dallas (PAD) is one of the most respected clinics in the Dallas area, and has been providing pediatric primary care since 1971. The practice priority of PAD, since its formation in 1971, has been to "dedicate itself to providing quality healthcare for children. [Their] goal is to create an environment where children feel welcome and parents feel confident in the care provided by PAD pediatricians. [They] strive to develop a trusting patient-physician relationship based on mutual understanding, communication, and caring. [Their] team is committed to delivering quality and compassionate care to generations of children in North Texas, based on seven core values: service, excellence, respect, vision, integrity, compassion, and empathy." This busy practice is comprised of 13 physicians working at two locations. PAD physicians perform up to 16 well-child visits, and see as many as 30-40 patients, in a full day. The practice accepts private insurances only, including most preferred-provider and health-maintenance organizations, and does not accept Medicaid. Twelve of the PAD pediatricians are Caucasian, and one is Latino and speaks Spanish fluently. PAD's patients are predominantly Caucasians; there also are substantial proportions of Asian and Indian patients, but lower proportions of Latino and African-American patients than in the academic and community clinic practices. PAD will collaborate closely with Dr. Briner on the proposed projects, with the guidance of Dr. Dreiling, who will facilitate interactions with other PAD physicians, administrative staff, and medical records personnel to ensure successful participant recruitment, data collection, and videorecording of well-child visits (see Letter of Support from Dr. Dreiling).

The **Center for Human Nutrition** promotes nutritional education for health professionals, conducts scientific research, and develops programs. The Center was established through the creation of an endowment fund for UT Southwestern to use in developing a program "to place the entire field of nutrition on a firm scientific foundation." The Center for Human Nutrition promotes the teaching of nutrition at all levels of UT Southwestern Medical Center. In addition to improving the general curriculum of medical students and Master's in Clinical Nutrition students, the Center for Human Nutrition upgrades understanding in the entire medical community with seminars and other scientific presentations. The nutrition center brings to the Dallas community an active educational program that includes clinical consultation for treatment of patients with specific problems, such as obesity, and dietary risk factors, a program for industrial organizations involved in preparation of food products, and a campaign for public education that includes seminars and media presentations. Research facilities on the Center for Human Nutrition include laboratories at both UT Southwestern Medical Center and the Veterans Medical Center in Dallas. In 1985, the Center moved into a new biomedical research building on the UT Southwestern campus. The Center has 8,000 square feet of laboratory space at UT Southwestern and a 2,000 square-foot laboratory at the VA Medical Center. Both facilities are equipped with modern and sophisticated research equipment.

The **Department of Clinical Sciences** provides an academic, educational, and cultural home for clinical investigators across all departments and disciplines at UT Southwestern. The infrastructure and function of the Department of Clinical Sciences is similar to that of other interdepartmental multidisciplinary centers focused on individual diseases; however, the goals of the Department are broad-based and encompass all clinical research throughout UT Southwestern. The mission of the Department is to promote the conduct of high-
quality patient-oriented research, develop effective mechanisms to facilitate translational research, provide a formal mechanism of institutional recognition for clinical scientists, and accelerate and enhance the training and career development of clinical investigators. The Department’s Division of Outcomes and Health Services Research (in which Dr. Flores has a secondary appointment) is dedicated to identifying, supporting, and disseminating evidenced-based healthcare practices that improve outcomes. The Department also includes the Division of Behavioral and Communication Sciences, Division of Ethics and Health Policy, Division of Biostatistics, Division of Community Health Sciences, and the Division of Biomedical Informatics, and offers courses in clinical research, biostatistics, ethics, health services research, and epidemiology. The Department of Clinical Sciences also supports the career development of individuals dedicated to a career in clinical investigation, and who aspire to develop into future leaders in clinical research. will have full access to these resources for the completion of the proposed career development award activities.

Research Environment, Facilities and Equipment

The Johns Hopkins Bloomberg School of Public Health and Department of Health, Behavior and Society

The Johns Hopkins Bloomberg School of Public Health (JHSPH) offers programs at the master's and doctoral levels through its ten academic departments: Biochemistry and Molecular Biology; Biostatistics; Environmental Health Sciences; Epidemiology; Health Policy and Management; Health, Behavior and Society; International Health; Mental Health; Molecular Microbiology and Immunology; and Population, Family and Reproductive Health. JHSPH is dedicated to improving health and preventing disease and disability worldwide, and has a strong commitment to the education of research scientists and public health professionals. Its faculty includes leading research experts in the fields of biostatistics, epidemiology, health services research, health education, health communication, sociology, anthropology, health economics and finance, health law and ethics, medicine, nursing, operations research, political science, psychology, policy analysis and public health practice.

The Department of Health, Behavior and Society (HBS; Dr. David Holgrave, Chair) was established in 2005 in order to conduct research and training to improve the understanding of how behavior and the societal context impacts health. Faculty in the department are involved in numerous national and international committees and study sections and are particularly interested in public health challenges associated with the top international and domestic causes of death and health issues that affect racial, ethnic and vulnerable communities in particular. The main core competencies of the HBS department are to:

1. Identify individual, organizational, community and societal influences on health, health behaviors, disease, injury, illness, and disability.
2. Develop, implement and evaluate behavioral and structural interventions to prevent disease and injury, alleviate illness and disability, improve the quality of life, and reduce health disparities.
3. Conduct and disseminate rigorous and innovative social and behavioral science research of relevance to public health.

Institutes and Research Centers

The clinical and research environment at the Johns Hopkins University and at the Health Institutions is rich and diverse, and is comprised of more than 50 institutes and research centers. The world-renowned research resources are located on 42 acres in East Baltimore, Maryland and are encompassed in the Hospital, the Schools of Medicine, Public Health, and Nursing, the Kennedy Institute, and the Welch Medical Library. The Schools of Public Health, Nursing, and Medicine share a 5 square block campus with the 1,036-bed Johns Hopkins Hospital and the Welch Medical Library.

Much of the Johns Hopkins School of Public Health faculty research is situated within specific centers for excellence in research. A few select and relevant centers are described below that provide unique opportunities for student participation in faculty research as well as seminars and studies. These include: the Institute for Global Tobacco Control, the Johns Hopkins Evidence-Based Practice Center, the Center for Adolescent Health, the Health Services Research and Development Center, and the Phoebe R. Berman Bioethics Institute of Johns Hopkins University. Each of these resources is briefly described below.

Institute for Global Tobacco Control

The Institute for Global Tobacco Control works to prevent death and disease from tobacco use through research, education and policy development. It focuses on leading and collaborating on research projects that support the development of tobacco control policy and interventions, serving as an educational resource through the collection and dissemination of material, developing and offering educational
programs, and synthesizing evidence in support of stronger tobacco control initiatives worldwide. Established in 1998 in the Department of Epidemiology at the Johns Hopkins Bloomberg School of Public Health, the Institute has a strong base in survey research. With ongoing projects in more than 40 countries around the world, the Institute serves as a key international resource for the development of global tobacco control policies and interventions. In 2004, the Institute was named a World Health Organization Collaborating Centre on Tobacco Control Surveillance and Evaluation. In 2008, the Institute moved to the Department of Health, Behavior and Society.

The Johns Hopkins Evidence-Based Practice Center
The Johns Hopkins Evidence-based Practice Center (EPC) is one of 13 centers designated in 2002 by the Agency for Healthcare Research and Quality (AHRQ). The primary mission of the Johns Hopkins Evidence-based Practice Center (EPC) is to generate, assemble, and synthesize knowledge and evidence necessary for the effective and efficient application of medical and public health practices. To accomplish this, the EPC integrates clinical expertise with comprehensive expertise in evidence-based methods including formal literature review, meta-analysis, decision analysis, and cost-effectiveness analysis. The EPC is based in the Welch Center for Prevention, Epidemiology, and Clinical Research and the Department of Epidemiology at the Johns Hopkins Bloomberg School of Public Health. The Welch Center is a collaborative effort of the Johns Hopkins School of Medicine and the Johns Hopkins Bloomberg School of Public Health.

EPC faculty have comprehensive experience in clinical, epidemiologic, and health services research. Faculty have performed assessments of the effectiveness and cost-effectiveness of new drugs, devices, and procedures and the decision-making criteria and processes used by managed care organizations to make technology coverage decisions. Faculty have also been involved in the translation of evidence-based knowledge into clinical practice and health policy.

Center for Adolescent Health
The Center for Adolescent Health is committed to assisting urban youth to become healthy and productive adults. Together with its community partners, the Center conducts research that identifies the needs and strengths of young people and tests programs designed to promote their health and well-being. The mission of the center is to work in partnership with youth, people who work with youth, community residents, public policy makers, and program administrators to help urban adolescents develop healthy adult lifestyles. The center's objectives are to improve the health and well-being of young people in the community; collaborate with the local community to conduct real-world research that advances healthy adolescent development; ensure that research results are readily available for practical application in the community; connect with other youth-serving organizations who share a common vision; and disseminate Center work to the broader community.

Health Services Research and Development Center
The Health Services Research and Development Center was established in 1969 to provide a locus for research on the organization, financing, staffing and technology of health services and their impact on the use, cost, and quality of the care they offer and on patient outcomes. The Center seeks to advance knowledge about effective and efficient approaches to providing health services to all people. To that end, it undertakes methodological and policy-relevant research in local, regional, and national venues. The Center's research program emphasizes interdisciplinary research on timely issues facing the American health care system. Priority is given to research on Federal and state policy issues, managed health care, and the assessment of quality and patient outcomes. Special attention is devoted to the role of preventive services and to the impact of health policies and services on vulnerable population groups such as children, the elderly, uninsured, mentally ill, and disabled persons.

The Phoebe R. Berman Bioethics Institute of Johns Hopkins University
Established in 1995, the Phoebe R. Berman Bioethics Institute seeks answers to ethical questions by promoting research in bioethics and encouraging moral reflection among a broad range of scholars, professionals, students, and citizens. The Institute serves the entire Johns Hopkins University and Health System and provides an intellectual home for faculty in all divisions whose research advances bioethical inquiry and whose teaching enables students and trainees to advance their understanding of bioethics in their personal and professional lives. This interdivisional approach reflects the Institute's position that bioethical issues transcend narrow disciplinary concerns, and that fruitful discourse requires broad based
Principal Investigator/Program Director (Last, first, middle) Tiner, Christy, Boling

scholarly exchange. The Bioethics Institute sponsors a variety of lectures, symposia, and discussions. The faculty of the Bioethics Institute teaches courses, seminars, and "ethics rounds" in the schools of Arts and Sciences, Medicine, Public Health, and Nursing. Recent areas of faculty research include AIDS, advance directives, reproductive rights, privacy and advances in genetics, managed care, the rationing and allocation of resources, and research ethics.

Computer Facilities
The Department of Information Systems serves as the central computing resource for the School of Public Health. The department provides computer hardware, software and support services for public health instruction, research computing and administrative use. The department provides email, calendar, and other Web applications through a secure portal, my.jhsph.edu. The primary server platforms are SUN Unix and Microsoft Windows. All desktop computers are connected to a 10MB switched Ethernet network. All computers are equipped with software for word processing and spreadsheets and internet access. In addition all computers have network access to statistical software including STATA, SAS, SPSS, M-PLUS and Epilinfo. All computers are equipped with software for word processing and spreadsheets and have internet access. Access to these systems is provided at three computer labs with 86 IBM personal computers. These facilities are available 24 hours per day, seven days per week. A wireless network is also available for use with laptops and other smaller computer devices. Free printing and wireless printing is also available in these facilities.

Professional Resources
The Johns Hopkins Medical Institutions Professional Development Office supports the professional and career development of JHSPH graduate students by offering an intensive four-day course in biomedical communication, designed especially for graduate students. This course focuses on topics that are critical to a successful academic career: grant writing, writing a research paper, and giving an oral presentation.

Library System
The book collections at the Johns Hopkins University consist of almost one-half million volumes. The books have been selected to support the studies of all the departments and divisions of the university.

The William H. Welch Medical Library
The William H. Welch Medical Library provides a variety of resources that support the research, teaching, and patient care goals of the Johns Hopkins Medical Institutions (JHMI) and the Johns Hopkins University. Students, who register as a library user, can search a range of databases and take advantage of the library information services and classes. The Welch Gateway is available 24 hours per day via the JHMI network or a modem connection. Library cardholders are also eligible for a personal e-mail account on the library Internet host computer, Welchlink. The library owns 367,000 books and journal volumes, 2,300 audiovisual programs, and subscribes to approximately 3,600 biomedical journals. Interlibrary loan and document delivery services are provided to library cardholders. Photocopy machines are located at all Welch service sites, and microcomputers and selected software are available to library users. The computer laboratory is equipped with 22 IBM PCs, 2 WELMED (Welch database) terminals, 8 interactive videodisk workstations, printers, modems, and file service.

The Abraham M. Lilienfeld Library
The Lilienfeld Library is the primary resource located within the School of Public Health and is managed by the William H. Welch Medical Library. It contains books, journals and other information relevant to the fields of public health, social sciences and behavioral sciences. This library also offers access, via the Johns Hopkins Medical Institutes online catalogue and specialized bibliographic databases, to information in all areas of interest to students. The total library collection is now approximately 30,000 volumes of books, pamphlets, and government reports. The library currently receives approximately 275 periodicals.

The Milton S. Eisenhower Library at Homewood
The Milton S. Eisenhower Library at Homewood (the main Johns Hopkins University campus) ranks as one of the nation's foremost research facilities. Carefully assembled to support the academic and research efforts of the University, the library's collection of over 2.3 million printed volumes and 3.3 million microfilms are distinguished by their breadth, depth and diversity. Significant collections of monographs, periodicals, and newspapers are supplemented by a large holding of digital information, video materials, maps, government publications, legal materials, manuscripts, archives, and other rare, special or valuable materials. Of particular interest are the collections in the social, physical and life sciences. The library also provides easy access to a wide selection of electronic information resources including the library's computerized catalogue, and electronic resource center with numerous abstracting and indexing tools and full-text files, and a World Wide Web gateway to the internet. Many of the databases are accessible remotely through JHUniverse, the University's electronic information system.
EQUIPMENT

[Redacted] has access to digital audio and video equipment through the Division of General Pediatrics (three digital audio recorders and one small video camera [Sony HDR-CX210 digital HD video camera recorder]), and the study statistician has a fast (2.66 GHz) desktop computer (Dell OptiPlex 755 Minitower) with 4 GB of memory and 800 MHz of RAM. This computer is loaded with the most recent versions of the state-of-the-art statistical software needed for all study analyses, including SAS, STATA, and SUDAAN, and the software licenses are renewed annually or as needed by the Division Director/primary mentor.

Computer Facilities-Johns Hopkins
The Department of Information Systems serves as the central computing resource for the School of Public Health. The department provides computer hardware, software and support services for public health instruction, research computing and administrative use. The department provides email, calendar, and other Web applications through a secure portal, my.jhsph.edu. The primary server platforms are SUN Unix and Microsoft Windows. All desktop computers are connected to a 10MB switched Ethernet network. All computers are equipped with software for word processing and spreadsheets and internet access. In addition all computers have network access to statistical software including STATA, SAS, SPSS, M-PLUS and Epilnfo. All computers are equipped with software for word processing and spreadsheets and have internet access. Access to these systems is provided at three computer labs with 66 IBM personal computers. These facilities are available 24 hours per day, seven days per week. A wireless network is also available for use with laptops and other smaller computer devices. Free printing and wireless printing is also available in these facilities.
LIST OF REFEREES

1. Helen H. Hobbs, MD
   Professor of Medicine
   UT Southwestern Medical Center, Dallas

2. Ken Cooper, MD
   Founder, Cooper Clinic
   A Cooper Aerobics Company, Dallas

3. Scott M. Grundy, MD, PhD
   Professor of Medicine
   Director, Center for Human Nutrition
   UT Southwestern Medical Center, Dallas

4. Elizabeth Parks, PhD
   Associate Professor of Medicine
   UT Southwestern Medical Center, Dallas

5. William S. Yancy, Jr., MD, MHSc
   Associate Professor of Medicine
   Duke University, Durham
A. Personal Statement

The goal of the proposed Career Development Award is to identify specific clinical practice elements and pediatrician-patient communication content that predict improvement in weight status among overweight, school-age children. Specifically, I plan to measure improvement in body mass index (BMI) percentile for age and gender and BMI standard deviation scores in a group of overweight children in primary care. I have the motivation, abilities, and training required to successfully conduct the proposed research. As a fellow in health services research at Duke University, I received training in clinical research design, research management, biostatistics, and research ethics through the Duke Clinical Research Training Program. I was mentored by experienced weight-loss interventionists, and participated in conducting and analyzing longitudinal, randomized dietary interventions in children and adults, and an observational cohort study that audiotaped medical dialogue directly. For my Master's thesis, I performed a secondary analysis of a randomized clinical trial using longitudinal mixed-model statistical methodology; I presented related work at two national meetings and published a first-authored, peer-reviewed research letter. I also collaborated on two NIH-supported studies: the Weight-Loss Maintenance trial (PI, Laura Svetkey) that examined predictors of improvement in insulin resistance in individuals who lost weight and Project CHAT (Communicating Health Analyzing Talk; PI Kathryn Pollak) that provided valuable information about patient-provider communication of weight-loss information, and what types of communication are most effective in promoting behavior change in adults. My role on Project CHAT was to serve as one of two physician coders that developed a codebook of communication themes, including counseling regarding diet, activity, self-monitoring, and other weight-loss recommendations. As a result of these previous experiences, I am aware of the importance of regular communication and meetings with project members, constructing realistic timelines for planned research and paper products, and managing budgets. Additionally, from Project CHAT, I learned about the importance of using validated, well-defined study measures; of minimizing participant drop-out; and of the strengths and limitations of using directly-recorded medical dialogue, including the loss of recordings, and the loss of the richness of communication content when applying strict quantitative methodology to predict health outcomes. On joining the UT Southwestern faculty, I shifted both my research and clinical focus to children, which somewhat disrupted my research productivity. To garner preliminary support for a dietary intervention, we conducted focus groups with parents of overweight, school-age children to determine their preferences regarding weight-management strategies for their children, including what they expected from their child's pediatrician. We found that parental expectations for the pediatrician included counseling regarding healthy diet and activity behaviors (not specific weight-loss diets), guidance regarding health risks, and consistent follow up with the child. Because the proposed dietary intervention recommended that children drink 2-3 cups of milk, the next study examined the prevalence of low vitamin D levels in a nationally-representative sample of children (enrolled in NHANES), and evaluated whether milk intake was associated with a lower prevalence of vitamin D deficiency. Vitamin D deficiency was found to be highly prevalent in overweight and obese children, and greater milk intake was associated with a lower risk of vitamin D deficiency. A first-authored, peer-reviewed research article was published in Pediatrics in January 2013. Additional research was conducted that informs the proposed research. I also analyzed the Medical Expenditure Panel Survey (MEPS), a widely-used national dataset, to examine the impact of pediatric...
overweight in US children on health, healthcare utilization, and expenditures. We found that overweight children reported poorer health and obese children had more emotional/behavioral problems. Despite these problems, health-services use was slightly higher for obese children only, and total expenditures were not different, suggesting that early intervention could prevent future increased costs. The study also highlighted key outcomes that could be evaluated during primary care and used in the design and assessment of weight-management interventions. In summary, through my training and research, I have gained experience with a diversity of research and statistical methods, and practical considerations in collaborating on NIH-supported research studies. The current proposal builds logically on my prior research and preliminary studies, and my training, experience, and research endeavors have prepared me to successfully lead the proposed project.

B. Positions and Honors

Positions and Employment

01/10 – Instructor in Pediatrics, Division of General Pediatrics, Department of Pediatrics, UTSW and Children’s Medical Center Dallas
01/10 – Instructor in Internal Medicine, Division of General Internal Medicine, UTSW and Parkland Health and Hospital System

Other Experience and Professional Memberships

2003 – Member, The Obesity Society
2004 – Member, American Academy of Pediatrics
2004 – Member, American College of Physicians
2004–2008 Resident Representative, Internal Committee on Graduate Medical Education, Duke
2006–2008 Resident Representative, Pediatric Nutrition Curriculum Committee, Duke
2006 – Chair-elect (2013-2014), The Obesity Society Clinical Management Section
2007 – Section Member, The Obesity Society Pediatric Obesity Section
2007–2009 Member, Global Pediatric Obesity Working Group, Project Director Dr. Mike Merson, Duke
2008–2010 Member, Society of General Internal Medicine
2008 – Member, American Board of Pediatrics
2010 – Member, American Board of Internal Medicine
2010 – Member, Academic Pediatric Association
2010 – Member, American Society for Nutrition
2010 – Member, Dallas Obesity Action Coalition
2011 – Member, AAP Provisional Section on Obesity
2012 – UT Southwestern Liaison, Texas Pediatric Society, Committee on Childhood Obesity

Honors

- AIURP/Merck Fellowship, Loyola Marymount University (1996)
- Outstanding Organic Chemistry Student of the Year, LMU, American Chemical Society (1997)
- Outstanding Graduate of the Year in the Natural Sciences, LMU (1998)
- Riordan/EPIC Award for Outstanding Service and Leadership (1999)
- President, Alpha Sigma Nu, Jesuit Honors Society, LMU Chapter (2010)
- Inducted into American Society for Nutrition (2010)
- Faculty mentor for award-winning medical student poster presentation, 49th Annual Medical Student Research Forum poster competition, UTSW (2011)
- Dannon Nutrition Leadership Institute (2011)
- Chair-elect, The Obesity Society Clinical Management Section (2013-2014)

C. Selected Peer-reviewed Publications

Most relevant to the current application


**Additional recent publications of importance to the field (in chronological order)**

**Other Publications**


**Book Chapters**


Published Abstracts, Posters, and National Presentations

1. Montaño S, Turer CB, Hoang K, Flores G. The wait for the weight: Pediatrician’s communication about weight to overweight and obese Latino children and their parents. E-PAS2013:3635.4 Accepted as a platform presentation at the 2013 Pediatric Academic Societies (PAS) meeting.

2. Turer CB, Hoang K, Montaño S. Don’t drink your calories: What pediatricians say about diet during primary-care visits with overweight school-age children. E-PAS2013:3807.172 Accepted as a poster at the 2013 PAS meeting.

3. Turer CB, Lin H, Flores G. Importance of vitamin D for height and physical functioning in US adolescents overall, but not overweight adolescents. E-PAS2013:1509.122 Accepted as a poster at the 2013 PAS meeting.


D. Research Support None
1. INTRODUCTION TO REVISED APPLICATION

I thank the Study Section for their thoughtful suggestions, the integration of which has greatly strengthened this resubmission. In this revision, all of the helpful suggestions of the three reviewers (Rev.) have been incorporated (changes are indicated by italics in the text and the location of changes as section.paragraph.line, in response to each “Weaknesses” bullet in sequence in the Summary Statement).

1. CANDIDATE: Rev 1. Regarding my publication record, three new first-authored publications (one in Pediatrics and two in Academic Pediatrics) and three new abstracts (one platform presentation and two posters) have been added to my Biosketch. The importance and relevance of my prior research to the proposed project was clarified (2.2.1-32). My prior training and publications focus on obesity and related comorbidities, and the new abstracts report findings from preliminary studies of pediatrician-patient communication (11C.2.10-25). Rev 2. See Rev 1 comment.

2. CAREER DEVELOPMENT PLAN: Rev 1. Additional details have been added regarding how meetings with mentors fit into the research plan. In the table detailing career-development award objectives and tasks, a column titled “Mentors” describes the specific mentor and/or advisor who will oversee the execution of the objective (4. Table). The frequency of meetings has been specified (4B-D). To ensure sufficient mentorship to successfully implement the projects and sustain future funding, Deb Wiebe (at UTSW) will serve as a mentor, instead of an advisor (4B.17-22). Rev 2. Information is provided regarding how the proposed courses are distinct from prior Master’s courses (3.2.3.5 and 3.2.12-14). Rev 3. A formalized plan for professional development (3.1.1-11 and 3.5.1-18) and an additional clinical-trials course, which provides comprehensive clinical-trials training, have been added (4A.2.6-7).

3. RESEARCH PLAN: Rev 1. 1) We clarified how the aims are based on AAP guidelines (10.2.1-7, 11B.2-8), how 5-2-1-0 behaviors will be measured coded (11C.Fig. 2, 11C.2.15-20, and Appendix 2 [see Participant Measures]), preliminary data on which the research aims are based (11C.2.6-33), and the trajectory for the research (3.1.2-11, 3.5.1-18, and 11H.1-4). 2) Both pediatricians and patient-participants will be masked in the Aim 2 study (11E.2.1-5). To control for reactivity to being videotaped, video cameras that are tiny and wall-mounted will be used (11E.9.2-5). 3) The rationale for masking is explained in more detail, and post-study debriefing of participants was added (11E.2.1-11 and 11E.2.11-14). 4) It is now highlighted that we will examine the associations of time to first follow-up for overweight/obesity, and the number, frequency, content, and nature of follow-up visits, with weight-status improvement and behavior change (11E.1.5-9 and 11E.2.6-11). Sustainability of weight-status improvement and behavior changes will be examined by looking at one-year outcomes (11E.1.19-20).

Rev 2. 1) More information about characteristics of the providers, practice priorities, and patients will be collected (see Facilities section). 2) Time to first follow-up for overweight/obesity, and the number, frequency, content, and nature of follow-up visits will be reported (11E.2.6-11). 3) The clinic site was added as a matching criterion (11D.3.1-3). 4) Although parent-based covariates, such as education and obesity, cannot be included in the Aim 1 study (they are not in the EMR), child-based covariates, including interval illnesses, will be included in both Aims 1 and 2 studies (11D.6.1-2 and 11E.6.2-4), and parent-based covariates associated with weight change will be included in the Aim 2 research (11E.Figure 4 [Measures/Outcomes: Child and Parent]).

5) We now will explore how recommended national guidelines for preventative care are implemented in the various practices (11E.9.7-9). 6) Although communication is video-recorded at one time point, the frequency of reinforcement likely is an important component for behavior change; we therefore will assess whether the time to first follow-up, and the nature of follow-up visits predict improvement in weight status in the Aims 2 and 3 studies (11E.2.6-11 and 11F.5.6-8). 7) For Aim 3, we now will test the feasibility, acceptability, and comparative effectiveness of various components of the intervention (clinical practice elements, including BMI and risk-factor screening and communication, more frequent follow-up visits, and patient-centered communication strategies), using a pilot RCT, instead of the previous clustered RCT design (11F.2.1-13). Rev 3. 1) The figures have been enlarged. 2) Preliminary data were added on the feasibility of working with the CMC database (11D.2.1-4). 3) Feasibility data for Aim 2 were added (11C.2.10-25). 4) We now address the potential limitation posed by the Hawthorne effect for Specific Aim #2 (11E.8.1-6). 5) The recruitment strategy and number for Specific Aim #2 have been clarified (11E.3.1-14).

4. MENTORS/CONSULTANTS: Rev 2. A community pediatrician was added (see Letters of Support [LOS]).

5. ENVIRONMENT/INSTITUTIONAL COMMITMENT: Rev 1. The PI’s mentor submitted a letter requesting the PI’s promotion from Instructor to Assistant Professor (See LOS). Rev 3. The CTSA has been removed.

6. PROTECTION OF HUMAN SUBJECTS: 1) A post-study debriefing of participants for the Aim 2 study was added (14A.1.5.7-8 and 14A.2.3.12-13). Pediatricians and participants will not be masked in the Aim 3 study. 2) A DSMB will be convened for the Aim 3 study (14A.2.8.9 and 14D.3.2-3).
2. CANDIDATE’S BACKGROUND

I am committed to an academic career in research focusing on developing and testing primary care weight-management interventions for overweight (OW) children. My dedication to a career in weight-management research can be traced back to childhood experiences that fueled my decision to go to medical school. During medical school at Johns Hopkins, to better understand metabolism, I completed a summer research fellowship in the biochemistry lab of Dr. Daniel Lane, I sought out and shadowed bariatric physicians and surgeons, and I joined the Obesity Society. I developed an understanding of obesity-related metabolic derangements, weight-management treatment options, and the important challenge of addressing obesity in children and families. After completing a combined internal medicine/pediatrics residency at Duke University, I expanded my clinical and research skills through a health services research fellowship, during which I was mentored by Drs. William Yancy and Laura Svetkey, leaders in dietary weight loss and weight-loss maintenance clinical trials. I also completed a Master’s in Clinical Research. Coursework for the degree included hands-on training in clinical research design and management, biostatistics, ethics, and other topics pertinent to a clinical-research career. For my Master’s thesis, I used mixed-model statistical methodology to examine predictors of blood pressure effects from two weight-loss interventions. I presented results from this work at two national meetings, and published a first-authored, peer-reviewed research letter. I also collaborated on the NIH-supported study Project CHAT (Communicating Health Analyzing Talk), which recorded physician-patient communication during primary care visits to determine communication styles that promote weight loss in adults. These opportunities positioned me for my faculty position at UT Southwestern in Pediatrics and Internal Medicine. Towards my goal of becoming a national expert in primary care weight-management interventions, I care for OW children in primary care and a weight-management clinic, and teach medical students and residents how to assess/treat OW patients in primary care. My internal medicine training has proven to be a great asset for using drugs to treat “adult diseases” in OW children. In fact, I have learned that sometimes the act of starting a medicine elicits behavior change successfully where simple counseling failed. Fewer children than I expected, however, have conditions that warrant medications. And when families hear that their child does not have a condition warranting treatment other than weight loss, some seem less invested in making lifestyle changes.

These observations led me to ask, what are the costs and consequences of childhood OW, and what might be effective weight-management solutions? To answer the first question, I used a national dataset (MEPS) to evaluate the association between OW and obesity and parent-reported health status, healthcare utilization, and expenditures. Study results suggested that pediatric OW and obesity impact child health status, emotional/behavioral problems, and specific domains of healthcare utilization, but do not appear to be associated with total healthcare expenditures. These findings highlighted the need for early intervention in OW children, when healthcare expenditures may not be greater. Study results were presented as a platform presentation at the 2011 national PAS meeting, and resulted in a first-authored research article. Next, a specific obesity consequence that I noted among children in the weight-management clinic was vitamin D deficiency, raising the question of whether vitamin D screening should be conducted in primary care. Because I could not determine the pre-test probability of vitamin D deficiency using the extant literature, I examined the prevalence in a nationally-representative sample of children. I found that vitamin D deficiency was highly prevalent in OW children, and was particularly high in severely-obese and minority children. A first-author article was published in Pediatrics. The MEPS and vitamin D studies provided key health/behavior and healthcare-use constructs that could be used to engage patients/parents when communicating regarding weight and weight-management. To identify effective weight-management solutions, I used focus groups to determine parental preferences for primary care weight-management interventions for OW children, including the role of the pediatrician. Parents wanted pediatricians to communicate directly regarding a child’s OW status, associated health risks, and recommended healthy behaviors, and to follow-up regularly with the child to assess weight improvement. Results from this study were presented as a poster presentation at the 2012 PAS meeting; a first-authored manuscript is under review. Next, I video-recorded primary-care visits to examine how pediatricians and parents/OW patients communicate regarding weight. Data from this study suggest that most pediatricians discuss weight-management with OW children, but few use the AAP-recommended “5-2-1-0” educational message, which includes, eat five fruits/vegetables daily, limit screen time to ≤2 hours/day, be physically active ≥1 hour/day, and no sugar-sweetened drinks. Results from this study were accepted for presentation as a poster at the 2013 PAS meeting. Finally, I used baseline data from a weight-control intervention of OW mothers and their at-risk children to examine the proportions who met the AAP-recommended behavior goals for preventing obesity. I found that few mothers or children met the behavior goals, meeting more goals was associated with lower risk of maternal obesity, and children had a greater likelihood of meeting a behavior goal when mothers met the corresponding goal, resulting in a first-
authored research article. The study findings suggest that communicating with mothers about the importance of role-modeling the AAP-recommended goal behaviors may influence their weight and the habits of their child.

The proposed project will build on my previous research, generate pilot data to enhance the likelihood of future funding, provide crucial skills for designing and testing future weight-management interventions for OW children, and prepare me to become an independent investigator. I currently have 70% of my time protected for research activities, and spend the remainder providing clinical care and teaching. Should I be honored with this award, my division and department have committed to protecting 75% of my full-time professional effort (nine person-months) for the research and career-development activities outlined in this award. Given the potentially huge impact childhood obesity may have on the future health of children, and the dearth of effective interventions to treat these conditions, my academic interest in weight-management interventions for children targets an area in great need of research.
3. CAREER GOALS AND OBJECTIVES

My long-term goal is to become a nationally recognized expert and independent investigator on primary-care weight-management interventions for overweight (OW) children. I will identify what pediatricians can do to promote improvement in weight status in OW children, and develop and disseminate evidence-based interventions. In the short term, I plan to complete mentored research drawing on the strengths of mentors, advisors, courses, and UT SW to perform a series of studies to better understand and pilot test specific clinical practice elements and pediatrician-patient communication strategies that promote weight-status improvement in OW children to create a foundation for an R01 application to test a large-scale intervention that is designed to improve the weight status and healthy-lifestyle behaviors of OW children by improving how pediatricians communicate with and treat these children. These activities are carefully planned to ensure my success as an investigator capable of independently developing, completing, analyzing, and disseminating effective primary-care weight-management clinical interventions for OW children.

My clinical and research experiences with OW children and adults, coupled with training on conducting randomized weight-loss trials, including clinical trials design, management, and interpretation, provide me with a strong foundation from which to develop and test primary care weight-management interventions. My prior research and training have given me basic skills in participant recruitment, data collection and management, conducting analyses of large datasets, transcript-based qualitative analyses, and mixed-model analyses. My clinical work in primary care and in weight-management clinics has given me experience in discussing weight and weight management with patients, and assessing and treating OW and weight-related diseases. Furthermore, these experiences have led me to observe that caring physicians can inspire patients to embrace healthy behavior changes, and that physicians have many tools (including clinical practices, such as risk-factor assessment and communication) that have not been assessed for their impact on weight-status improvement. It is essential to identify these intervention components to advance the field of weight-management intervention research. To achieve my goal to become an independent investigator on weight-management interventions for OW children, I will need further training in multi-level modeling, survey development, analysis of health communication, child adherence, and intervention development.

My proposed career-development-award activities will build on my research and training thus far, advancing my research agenda and preparing me to become an independent researcher. My overall goal for this proposed award is to use quantitative multi-level modeling of primary care data, and Roter Interaction Analysis System (RIAS) of video-recorded well-child visits to identify specific clinical practice elements and communication strategies that improve weight status in OW children, and to use this information to develop and test a pilot intervention. These methodologies will be essential in my career as a childhood obesity researcher. The first aim of the proposed award is to use a case-control study to identify specific clinical practice elements that are associated with weight-status improvement among OW children. I will learn to analyze multi-level data through a secondary data analysis of the Children's Medical Center primary-care dataset. I have no formal training in multi-level modeling methodology, and desire focused instruction in this area. This research experience will be mentored by my primary mentor, Dr. Flores, who has extensive experience in multilevel modeling and health services research, and by my advisor, Dr. Barlow, an expert in the primary-care assessment and treatment of childhood OW and obesity. The research will be supplemented with didactic and one-on-one tutorials on quantitative methods, and with classes on multilevel modeling and analysis of binary-response and hierarchically-structured data.

The second aim is to determine pediatrician-patient communication strategies that predict weight-status improvement in OW children by using an observational cohort study in which well-child visits will be video-recorded, and children will be followed (by tracking health-services use in the EMR) for approximately one year. I will examine pediatrician-patient communication and survey answers to identify communication strategies in primary care that predict weight-status improvement among OW children. This experience will be mentored by Dr. Roter, who is the developer of RIAS methodologies and has more than 30 years of experience analyzing and teaching others how to analyze communication data, and by Dr. Flores, who has extensive experience with community-based recruitment, qualitative analysis, and working with diverse populations. This experience will be supplemented with an intensive tutorial on RIAS by Dr. Roter, and classes in health survey and cross-cultural clinical research. I will learn how to develop new survey instruments, and collect and analyze survey data under the mentorship of Dr. Wiebe, who also will instruct me on developmental and theoretical frameworks for understanding adherence in children with chronic diseases.

The findings from these studies will be used in the Aim 3 project to design and test the feasibility and acceptability of a pilot intervention aimed at improving pediatricians' use of the effective clinical practice elements and communication strategies identified in the Aims 1 and 2 studies. This research experience will
be mentored by Dr. Flores, an expert in conducting and analyzing community-based interventions, Dr. Barlow, an expert in primary-care assessment and treatment of childhood OW, and Dr. Wiebe, an expert in medical adherence in children. I will use the research and educational resources at UTSW to conduct these three studies and submit a future R01 grant to implement a large-scale intervention to improve the weight status and healthy-lifestyle behaviors of OW children by improving pediatricians' use of effective clinical practice elements and communication content and strategies. With the combination of my prior training and the proposed career-development-award activities, I will have the skills to formulate an important research question, design a study using the appropriate methodology, use quantitative and RIAS data analysis techniques, devise instruments to measure constructs of interest, develop and implement a pilot intervention, and measure the effectiveness of the future, large-scale intervention using appropriate survey design and analysis. This will allow me to develop an R01 application for a large-scale randomized, controlled trial examining the effectiveness of an intervention to improve the weight status and healthy-lifestyle behaviors of OW children by improving pediatricians' communication and use of specific clinical practice elements when addressing weight/weight management in primary care, and provide me with the training to become an independent intervention researcher in the primary-care assessment and treatment of childhood OW and obesity.
### 4. CAREER DEVELOPMENT/TRAINING ACTIVITIES DURING PROPOSED AWARD

This proposed career development award will provide the necessary training and protected time to successfully execute the proposed research projects and acquire new skills regarding multi-level modeling, survey development, analysis of health communication, health behavior, child adherence, and intervention development. No more than 25% effort each year will be devoted to clinical and teaching activities.

<table>
<thead>
<tr>
<th>Objective</th>
<th>Course (C); Presentation/Publication (P); Task (T)</th>
<th>Mentor(s)</th>
<th>Year 1</th>
<th>Year 2</th>
<th>Year 3</th>
<th>Year 4</th>
<th>Year 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Responsible conduct of research</td>
<td>C: seminar: ethics grand rounds</td>
<td>Flores (F)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>C: ethics in clinical science</td>
<td>F</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>C: research ethics, biomedical science</td>
<td>F</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AIM 1</td>
<td>T: extract EHR data</td>
<td>Barlow (B), F</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clinical practice elements</td>
<td>T: clean and perform descriptive analyses</td>
<td>B, F</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>C: multi-level modeling (two courses)</td>
<td>F</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>T: perform multi-level modeling analysis</td>
<td>B, F</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>P: present findings/write manuscript on clinical practice elements</td>
<td>B, F</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AIM 2</td>
<td>T: recruit pediatricians and collect surveys</td>
<td>B, F, Wiebe (W)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Communication</td>
<td>C: health survey research</td>
<td>F</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>methods and content</td>
<td>T: analyze baseline pediatrician surveys</td>
<td>F</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>T: recruit participants, record visits, and collect baseline measures</td>
<td>B, F, Roter (R), W</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>P: present findings/write/submit manuscripts on baseline communication data</td>
<td>B, F, R, W</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>C/tutorial: Roter Interaction Analysis Training (Baltimore)</td>
<td>R</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>T: code recordings and determine inter-rater reliability</td>
<td>F, R, W</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>T: collect one-year follow-up measures/surveys</td>
<td>B, F, R, W</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>T: clean and analyze data</td>
<td>B, F, R, W</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>C: cross-cultural clinical research course</td>
<td>F</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>P: present findings/write/submit manuscripts on one-year communication data</td>
<td>B, F, R, W</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AIM 3</td>
<td>C: clinical research courses (two courses)</td>
<td>F</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pilot intervention</td>
<td>T: develop pilot intervention and submit protocol to IRB</td>
<td>B, F, R, W</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>T: recruit pediatricians, pilot intervention, and collect data</td>
<td>B, F, W</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>T: clean and analyze data</td>
<td>B, F, R, W</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>P: present findings/write/submit manuscript on pilot intervention</td>
<td>B, F, R, W</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Apply for R01</td>
<td>T: develop effectiveness intervention trial (grant application)</td>
<td>B, F, W</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**A. Coursework.** Ethics courses - See Training in the Responsible Conduct of Research (Section 5). Multilevel Modeling, University of Kansas. Five-day intensive training on designing multilevel studies and analyzing hierarchically-organized data, including estimating/interpreting random effects, multi-parameter tests, cross-level interactions, and modeling longitudinal data. Multilevel Models for Binary Responses, University of Bristol-online. Includes examining latent variables, random intercept/slopes, clustering effects. Health survey research course: Developing and Validating Measures in Clinical Research, UTSW. Survey design, development, and validation. Cross Cultural Clinical Research, UTSW. Strengthens skills in cross-cultural competencies necessary to design/implement research in diverse populations. Clinical Trials Research: From Proposal to Implementation: UTSW. Topics include recruitment, monitoring patient safety, data collection, and analysis. Advanced Clinical Research Design & Analysis, UTSW. Topics include specifying primary/secondary outcomes; surrogate measures; analysis of incomplete data; minimizing bias and flaws in study design.

**B. Mentors.** My primary mentor is Glenn Flores, Professor of Pediatrics, Clinical Sciences, and Public Health, and Director of the Division of General Pediatrics. Dr. Flores is an internationally known, NIH-funded researcher on obesity, RCTs, racial/ethnic disparities, access to healthcare, and the health and health of underserved children. He is an award-winning mentor who has mentored many faculty, including several junior faculty with NIH and foundation career-development awards. We will continue to meet weekly for 30-60 minutes to discuss my research projects and career goals. He will help me advance my skills in conducting ethical research, qualitative and quantitative methods, grant writing, manuscript writing, study design, and implementing protocols, and in transitioning into an independent investigator and leader in this field. Debra Roter, DrPh, MPH will be my senior mentor for understanding the theoretical frameworks in health communication, training in Roter-Interaction Analysis System (RIAS), and analyzing physician-patient communication. Dr. Roter is Professor of Health, Behavior, and Society at the Johns Hopkins Science, and Public Health, and Director of the Division of General Pediatrics. Dr. Flores is an internationally known, NIH-funded researcher on obesity, RCTs, racial/ethnic disparities, access to healthcare, and the health and health of underserved children. He is an award-winning mentor who has mentored many faculty, including several junior faculty with NIH and foundation career-development awards. We will continue to meet weekly for 30-60 minutes to discuss my research projects and career goals. He will help me advance my skills in conducting ethical research, qualitative and quantitative methods, grant writing, manuscript writing, study design, and implementing protocols, and in transitioning into an independent investigator and leader in this field. Debra Roter, DrPh, MPH will be my senior mentor for understanding the theoretical frameworks in health communication, training in Roter-Interaction Analysis System (RIAS), and analyzing physician-patient communication. Dr. Roter is Professor of Health, Behavior, and Society at the Johns Hopkins.
School of Public Health. She is a leader in the analysis of physician-patient medical dialogue, and the socio-behavioral aspects of CVD prevention. She has been funded for 30 years by NHLBI, NICHD, NCI, and NIMH in the field of physician-patient communication. In Year 1, I will have monthly conference calls with Dr. Rotter for 30-60 minutes for tutorials on health communication/communication content analysis and to discuss Aim 2 study progress, and I will meet with Dr. Rotter in Baltimore for intensive training on using RIAS. In Years 2-3 I will have monthly conference calls with Dr. Rotter, who will help me analyze, present, and write-up Aim 2 study findings. In Years 4-5, Dr. Rotter and I will have monthly calls regarding Aim 3 study development, testing, and communication of results, and translation of findings into a large-scale RCT for which I will seek R01 funding. Deborah Wiebe, PhD, will be my senior child adherence and health-psychology/behavior mentor. Dr. Wiebe is Professor in the Department of Psychiatry at UTSW. She is an internationally known researcher in adherence, and in child and adolescent health behavior. We will meet in person for 60 minutes twice monthly in Years 1-2 for tutorials on child psychological and behavioral theory, adherence theories, and to discuss survey development, administration, and analysis. She will be my primary survey methodology mentor. In Years 3-5, we will meet in person monthly to discuss survey data, validity, analysis, and interpretation.

C. Advisor. Sarah Barlow, MD, MPH is the lead author of the 2007 Guidelines for the assessment and treatment of childhood obesity, and will serve as my childhood obesity content expert and advisor. Dr. Barlow is Associate Professor in the Department of Pediatrics at Baylor College of Medicine in Houston. We will hold monthly 60-minute phone conferences, meet in person at least every three months, and meet at the Pediatric Academic Societies and the Obesity Society Meetings each year. Dr. Barlow's husband, Perry Bickel, is the Chief of the Division of Endocrinology at UTSW, and thus Dr. Barlow makes frequent trips to Dallas.

D. Meeting Schedule and Evaluation Plan. In addition to the meetings outlined above, I will have joint research meetings every three months with all of my mentors and advisor (Drs. Flores and Wiebe in person, and Drs. Rotter and Barlow will join by phone/conference call), during which I will discuss study progress, present my data, and discuss future projects. My research and career progression will be evaluated bi-annually. Twice yearly, I will provide the mentorship team with my career and research goals, including coursework, manuscript and national conference submissions, and grant applications. My mentors will collectively and individually provide a detailed evaluation of my progress. I will present my work at the UTSW Pediatric Departmental Research Conference, Generalist Research in Progress Conference, and Department of Pediatrics Grand Rounds. I will submit a minimum of five manuscripts from the proposed projects for publication; however, my goal is to submit 2-3 manuscripts per year during the course of the award period.
5. TRAINING IN THE RESPONSIBLE CONDUCT OF RESEARCH

I have completed training in Human Subjects Protection, HIPAA, and good clinical practice through the UTSW Institutional Review Board, and will re-certify every two years. Dr. Flores will supervise my instruction in the responsible conduct of research and provide additional guidance. I will maintain regular contact with the IRB reviewer assigned to my studies to receive guidance about, and appropriately resolve, any questions regarding responsible conduct of research. In addition, in Year 1 of the proposed award, I will complete the Ethics in Clinical Science course, consisting of bi-weekly interactive seminars (3.5 hours/month) for 12 months, led by faculty in the Division of Ethics (Department of Clinical Sciences) at UTSW and guest faculty, focusing on ethical issues faced by clinical scientists, including scientific integrity, ethics of subject recruitment, treatment versus research, informed consent, dealing with unexpected scientific and clinically-important findings, authorship order and publications, handling misconduct and fraud, and research with vulnerable populations. In Year 3, I will complete the Research Ethics in Biomedical Sciences course (1.5 hours/week for one semester), led by faculty in the Division of Ethics at UTSW, consisting of a conceptual and case-analysis approach to ethical issues, such as conflict of interest and misconduct. For the five years of the proposed award, I will attend monthly Ethics Grand Rounds (one hour/month) at UTSW, consisting of lectures by UTSW faculty in the Division of Ethics and visiting scholars, which address pressing bioethics issues, such as transparency and genomics, followed by interactive discussions.
Re: Division Chief and Primary Mentor Letter for K23 Application- [Redacted], MD, MHS

Dear Study Section Members,

I am delighted to write this letter in strong support of [Redacted] and her application for a K23 Award. As I am both Division Chief and Primary Mentor, this will be a combined letter for each of these roles.

DIVISION CHIEF SECTION

Applicant's Characteristics and Potential as a Productive Clinical Investigator

We recruited [Redacted] to join the Divisions of General Pediatrics and General Internal Medicine as a clinician-researcher because of her excellent research training and her research interests in obesity and its health consequences across the lifespan, with a particular focus on prevention and treatment of childhood obesity in primary care. Since joining the faculty in January 2010, she has published or has in press three first-authored articles and one research letter, co-authored five other articles, chaired a workshop at the 2010 Society of General Internal Medicine meeting, had a first-authored abstract presented as a platform presentation at the 2011 Pediatric Academic Societies (PAS) meeting, and had first-authored abstracts presented as a poster symposium and posters at the 2012 and 2013 PAS meetings; all of these products pertain to obesity. She has a superb knowledge of the literature on childhood obesity and obesity interventions, and manifests impressive creativity in her interdisciplinary approaches to research.

Institutional Resources Available to Candidate, Should She Receive a K23 Award

[Redacted]'s primary appointment is in the Division of General Pediatrics at UTSW, which consists of 16 faculty (including three clinician-researchers, two of whom have active NICHD K23s), four academic general pediatric fellows, and 13 staff. The Division has recognized national leadership in research, health policy, and advocacy regarding child health. As the Division Director and [Redacted] primary mentor, I have provided her with her own office (which is two doors away from mine) and computer, and access to our full-time PhD biostatistician, an administrative assistant, an experienced full-time Program Coordinator, and $30,000 in research seed money. All of these resources will continue to be available to Christy, should she receive a K23 Award. [Redacted] also has access to the UTSW Department of Clinical Sciences, and the Division of Internal Medicine (where she holds a secondary appointment in the Division of General Internal Medicine).

Proposed Distribution of Applicant's Time

I, along with Dr. Pérez-Fontan, Chairman of the Department of Pediatrics at UTSW (see his letter of support), currently protect 70% of [Redacted]'s effort for research, and will protect 75% of her effort for research, should she receive a K23 Award.
PRIMARY MENTOR SECTION

Prior Experience as Mentor and in Applicant’s Proposed Area of Research

Over the past 18 years, I have mentored 61 beginning clinical investigators, including 14 junior faculty, seven fellows, nine residents, 21 medical students, and 10 undergraduates, who collectively have published 69 articles (in peer-reviewed medical journals that include Pediatrics, Academic Medicine, Archives of Pediatrics & Adolescent Medicine, and the Journal of Pediatrics) and book chapters, made 46 platform and 58 poster presentations at national and regional meetings, have had 28 grants funded (including three career-development awards), and have received nine awards for research excellence. I currently mentor seven junior faculty, four fellows, and four medical students. A complete list of my mentees, including their products and current positions, is included as an appendix to this application. Three of my faculty mentees have obtained career-development awards, including two who hold active NICHD K23 awards.

I have extensive experience in the proposed areas of research for her K23 application, which include pediatric health services research, childhood overweight/obesity, communication issues, Latino children’s health, qualitative research, community-based research, and interventions targeting at-risk, underserved, and minority children. I am on the editorial board of Journal of Health Care for the Poor and Underserved, and previously served on the editorial board of Academic Pediatrics. I am past Chair of the Research Committee of the Academic Pediatric Association, a former member of the Committee on Pediatric Research of the American Academy of Pediatrics and the Institute of Medicine Committee on Pediatric Health and Health Care Quality Measures, and a current member of the US Preventive Services Task Force, American Pediatric Society Council, and the National Advisory Committees of the Robert Wood Johnson (RWJ) Amos Medical Faculty Development Program and RWJ Aligning Forces for Quality (AF4Q) Program. I was a member of the Expert Panel for the Department of Health and Human Services Health Care Language Services Implementation Guide, recently provided a Congressional Research Briefing, have testified in the US Senate on Latino health and the Hispanic Health Improvement Act, and provided invited written testimony on health disparities for the US House of Representatives’ Ways and Means Committee. I was an invited speaker at the National Summit on America’s Children convened by Speaker of the House Nancy Pelosi. I am a member of the Frew Advisory Committee for the Texas Health and Human Services Commission. I have served as a consultant and national advisory committee member for the Centers for Disease Control and Prevention, the US Surgeon General, American Medical Association, National Hispanic Medical Association, and the Sesame Street Workshop. I received the 2006 American Academy of Pediatrics Outstanding Achievement Award in the Application of Epidemiologic Information to Child Health Advocacy, the 2008 Millie and Richard Brock Award for Distinguished Contributions to Pediatrics, the 2010 Helen Rodriguez-Trias Social Justice Award from the American Public Health Association, and the 2012 Academic Pediatric Association’s Research Award. I have published 167 articles and book chapters on a variety of topics in such journals as JAMA, the New England Journal of Medicine, Pediatrics, and the Lancet, including three articles in the past year on childhood overweight/obesity in the Journal of the Academy of Nutrition and Dietetics, International Journal of Obesity, and American Journal of Clinical Nutrition, and almost all of my publications concern pediatric health services research and racial/ethnic disparities. Five of my last six major grants are for randomized trials examining the effectiveness of community-based interventions in improving child health, including a study of the effectiveness of community-based case managers in insuring uninsured children that was published in Pediatrics and resulted in a Congressional Research Briefing, a US Senate bill, and a portion of the CHIPRA legislation including community health workers as a means of insurance outreach and enrollment. My current research funding includes a five-year, $3 million NICHD R01 entitled, “A Randomized, Controlled Trial of the Effects of Parent Mentors on Insuring Uninsured Minority Children,” and an NIDDK R25 grant. I will leverage my experience from leading such large-scale interventions and in screening and prevention as a member of the US Preventive Services Task Force to benefit through mentorship, guidance, and networking in these areas.

Mentoring Plan and Commitment to Working with Applicant

I will continue to mentor you in 30-60 minute weekly sessions. I will provide her mentoring on project conceptualization and progress, patient-physician communication, multi-level modeling, large database analyses, interventions to address overweight in pediatric primary care, randomized controlled trials, statistical analyses, abstract preparation for scientific meetings, preparing and submitting manuscripts, grant preparation, career goals, promotion and tenure, managing project teams, and any other issues that she wishes to discuss. We also will continue to meet informally, as needed; with my office two doors away from mine, we often speak at least daily.
about project progress and other academic issues. [ ] will continue to participate in our weekly Generalist Research in Progress seminars, and to meet with any visiting researchers who are guests of the Division of General Pediatrics. Despite her prior research training, [ ] has limited experience with the examination and analysis of medical dialogue, multi-level modeling, and survey design. I will work with [ ] and our assembled team of co-mentors and advisors to assure that her career-development award activities fill these gaps in her training. Mentoring is one of the most important and rewarding elements of my professional life. I recruited [ ] for a junior faculty position here at UTSW, as I was impressed with her drive, training, talent, and skills. I have an unwavering commitment to working with [ ] and ensuring that she not only achieves great academic success, but also fulfills her vision of conducting research that makes a difference in the health and healthcare of overweight and obese children.

Funding and Other Resources Available to Support Applicant's Research

The substantial funding and resources available to support [ ] are detailed above in the section labeled, "Institutional Resources Available to Candidate." [ ] will have 75% FTE protected for research, $30,000 in research seed money, and the standard UTSW faculty Academic Development Funds of $3,000 per year.

Plan for Transitioning Applicant from Mentored to Independent Investigator

My current mentoring focus for [ ] is having her publish a series of articles on her interrelated research themes of assessment and management of childhood obesity and its health consequences, along with obtaining career-development funding. Her proposed K23 research program would allow her to conduct the crucial studies needed to properly set the stage for a strong application for an R01 grant or equivalent funding to design, implement, and evaluate a randomized, controlled trial of an intervention to improve pediatricians' communication competence in and enhance use of key clinical practice elements when addressing overweight in primary care.

Willingness to Provide Annual Evaluations of Applicant's Progress for Award Duration

Should [ ] receive the K23 award, I agree to provide annual evaluations of her progress for the duration of the reward, as required.

Summary

[ ] is a talented, well-trained clinician-researcher who brings a superb intensity, perseverance, and scholarly approach to all of her endeavors. A K23 award would be instrumental in her becoming a successful independent investigator, and I foresee her as a future star in pediatric obesity research.

Sincerely,

Glenn Flores, MD, FAAP
Professor of Pediatrics, Clinical Sciences, and Public Health
Director, Division of General Pediatrics
The Judith and Charles Ginsburg Chair in Pediatrics
Founder and Director, Academic General Pediatrics Fellowship
March 8, 2013

Dear Study Session Members,

I am writing this letter in reference to the application for the K23 Award. As a researcher with over 10 years of experience in the area of medical research, I am well aware of the limited evidence regarding effective communication strategies during well-child visits with overweight children. Therefore, I am very excited to serve as a mentor for the proposed career development plan and proposed research to improve pediatric-patient communication methods that predict improvements in weight status. I will provide the opportunity to analyze predictive communication patterns, and help guide [blank] in becoming a national leader in this field. [blank] has conducted an impressive array of preliminary work in obesity prevention and treatment, and has developed well-defined research plans. Her proposed research will move the field significantly closer to the development of effective primary care-based interventions that are effective in improving childhood overweight.

I am a Professor of Pediatrics, Health, and Society at the Johns Hopkins Bloomberg School of Public Health, and hold joint appointments as a Professor in the Johns Hopkins School of Medicine and Nursing. I have been continuously funded for 30 years of my research in physician-patient communication through the NIH, NIMH, NICHD, NCI, and Department of Veterans Affairs, and have authored over 200 peer-reviewed publications. I have conducted numerous studies evaluating the use of the diagnostic triangle to address the multifaceted reasons for the development of obesity. [Blank] will be the lead investigator on this project with the participation of [blank] and [blank] in the [blank] Project to improve patient communication. [Blank] will provide the opportunity to analyze predictive communication patterns, and help guide [blank] in becoming a national leader in this field. [Blank] has conducted an impressive array of preliminary work in obesity prevention and treatment, and has developed well-defined research plans. Her proposed research will move the field significantly closer to the development of effective primary care-based interventions that are effective in improving childhood overweight.

I am a Professor of Pediatrics, Health, and Society at the Johns Hopkins Bloomberg School of Public Health, and hold joint appointments as a Professor in the Johns Hopkins School of Medicine and Nursing. I have been continuously funded for 30 years of my research in physician-patient communication through the NIH, NIMH, NICHD, NCI, and Department of Veterans Affairs, and have authored over 200 peer-reviewed publications. I have conducted numerous studies evaluating the use of the diagnostic triangle to address the multifaceted reasons for the development of obesity. [Blank] will be the lead investigator on this project with the participation of [blank] and [blank] in the [blank] Project to improve patient communication. [Blank] will provide the opportunity to analyze predictive communication patterns, and help guide [blank] in becoming a national leader in this field. [Blank] has conducted an impressive array of preliminary work in obesity prevention and treatment, and has developed well-defined research plans. Her proposed research will move the field significantly closer to the development of effective primary care-based interventions that are effective in improving childhood overweight.

I am a Professor of Pediatrics, Health, and Society at the Johns Hopkins Bloomberg School of Public Health, and hold joint appointments as a Professor in the Johns Hopkins School of Medicine and Nursing. I have been continuously funded for 30 years of my research in physician-patient communication through the NIH, NIMH, NICHD, NCI, and Department of Veterans Affairs, and have authored over 200 peer-reviewed publications. I have conducted numerous studies evaluating the use of the diagnostic triangle to address the multifaceted reasons for the development of obesity. [Blank] will be the lead investigator on this project with the participation of [blank] and [blank] in the [blank] Project to improve patient communication. [Blank] will provide the opportunity to analyze predictive communication patterns, and help guide [blank] in becoming a national leader in this field. [Blank] has conducted an impressive array of preliminary work in obesity prevention and treatment, and has developed well-defined research plans. Her proposed research will move the field significantly closer to the development of effective primary care-based interventions that are effective in improving childhood overweight.

Sincerely,

[Signature]

Debra J. Voorhees, M.D.
March 3, 2013

Dear Study Section Members,

I am pleased to serve as a co-investigator for the career development project, "Primary Care, Overweight, and Improving Overweight Children's Weight Status," and have discussed the revised proposal extensively, and I am encouraged about the aims and research sites. Given the long-term trends of pediatric obesity and its effects, interventions should be put in place to address excess weight and obesity in children.

The proposed approach takes an innovative way to evaluate both "self" and "social" intervention. The intervention, though more difficult to study, is likely to be extremely important, and the proposal shows great promise in identifying strategies that will improve impact.

My role is to work closely with the primary care team. As a member of the Pediatric Research Group for the Expert Committee on Prevention, I have studied the evidence for obesity intervention. I am director of Texas Children's Hospital and Children's Ambulatory Pediatrics, and I have studied the evidence for obesity intervention. I am director of Texas Children's Hospital and Ambulatory Pediatrics. I have studied the evidence for obesity intervention. I am director of Texas Children's Hospital and Ambulatory Pediatrics.

I will provide advice on current best practices for evaluation and counseling to address excess weight and obesity in children. I will provide one-hour telephone calls each month. Every three months, on average, we will meet face-to-face at professional meetings in the Dallas area. We have had monthly telephone calls, and we will meet three times each month.

In the last submission of her application for a career development award, she included a letter from a local pediatrician, who is a member of the treatment writing group, and she received the approval letter from the Children's Hospital to serve as a co-investigator on the Pediatric Research Group. I expressed great enthusiasm that we write this letter in support of the proposed K23 award for the past two years. I am working closely with the Investigator in identifying patients for the study.

I, Nancy Kelly, have served as the Medical Director of the Children's Medical Center Continuity Clinic for the past 7 years, have successfully collaborated with researchers in patient-oriented research, and have served on the NHLBI Ambulatory Pediatrics Development Project. I am leading the development of the primary care component of a multilevel intervention for primary and secondary prevention of obesity in infancy and early childhood.

I, Nancy Kelly, have served as the Medical Director of the Children's Medical Center Continuity Clinic for the past 7 years, have successfully collaborated with researchers in patient-oriented research, and have served on the NHLBI Ambulatory Pediatrics Development Project. I am leading the development of the primary care component of a multilevel intervention for primary and secondary prevention of obesity in infancy and early childhood.

I look forward to working with [redacted] on this exciting project and am honored to be an advisor for her NHLBI K23 Career Development Award.
Dear Study Section Members,

It is with pleasure that I write this letter to state that I will serve as a pediatric community consultant for the proposed K23 research. I am a pediatrician who has practiced in the Dallas community for more than eight years, and have first-hand experience in the challenges facing pediatricians who regularly assess and treat overweight children in primary care. I will regularly discuss with Dr. Banner regarding how to address overweight/obesity among school-age children in pediatric primary care, and ensure that the research is answering important questions for community pediatricians in an ethical manner. I have read and discussed with Dr. Banner her proposed research, and provided input on the revised research application. Dr. Banner and I will continue to discuss her research, at least once every other month, throughout the course of the research projects. I look forward to working with her and contributing to identifying how pediatricians can provide the most effective care for overweight and obese children.

Sincerely,

[Signature]

Dr. Chen, M.D.

---

Los Barrios Unidos Community Clinic

NHLBI K23 Career Development Award Committee

Dear Study Section Members,

I am delighted to write this letter in support of Dr. Banner's application for the NHLBI Career Development Award. I am the Medical Director of the Los Barrios Unidos Community Clinic, and in my three years at Los Barrios as Medical Director, I have successfully collaborated on previous research projects. I will help Dr. Banner establish relationships with the Los Barrios administrative medical records, and medical staff to ensure successful recruitment of Los Barrios pediatricians and patients for her study. Los Barrios will serve as a practice site for Dr. Banner to conduct a secondary data analysis of medical records, survey pediatricians and patients, and video record well-child encounters. I will continue to facilitate relationships with the Los Barrios staff and patients to ensure successful recruitment and data collection for the studies proposed in her career development award. I am honored to be a collaborator for Dr. Banner on her career development proposal and look forward to continuing our collaboration, with the eventual goal of developing evidence-based strategies for the assessment and treatment of overweight and obesity in primary care.

Sincerely,

[Signature]

Susan Briner, MD Medical Director, Los Barrios Unidos Community Clinic

---

NHLBI Career Development Award Committee

Dear Study Section Members,

I am pleased to write this letter in support of Dr. Banner's application for the Career Development Award. I have been a Partner in the Pediatric Associates of Dallas practice since 2002, and our practice has successfully collaborated on previous research projects. Pediatric Associates of Dallas will serve as a practice site for Dr. Banner to videorecord well-child encounters. I will help Dr. Banner establish relationships with the Pediatric Associates of Dallas administrative and medical staff to support successful recruitment of Pediatric Associates of Dallas pediatricians and patients for her study. I will continue to facilitate relationships with the Pediatric Associates of Dallas patients to ensure successful recruitment and data collection for the studies proposed in her career development award. I am happy to be a collaborator with Dr. Banner on her proposed studies.

Sincerely,

[Signature]

Dr. Chris Dreiling, MD, FAAP, Partner, Pediatric Associates of Dallas
DESCRIPTION OF INSTITUTIONAL ENVIRONMENT

University of Texas Southwestern Medical Center

The University of Texas Southwestern (UTSW) Medical Center is ranked among the top academic medical centers in the world. The medical center has three degree-granting institutions: UTSW Medical School, UTSW Graduate School of Biomedical Sciences, and UTSW School of Health Professions. Faculty and residents provide care to nearly 97,000 hospitalized patients and oversee 1.8 million outpatient visits a year. The institution is home to several world-renowned faculty members including 4 Nobel laureates and 17 members of the National Academy of Sciences. Ongoing support from federal agencies such as the National Institutes of Health, along with foundations, individuals, and corporations provide more than $400 million per year to fund about 3,500 research projects. Collaborations between investigators across departments are encouraged and evident. UTSW Southwestern regularly organizes research forums to highlight the achievements of its faculty members and foster collaborations between investigators. The University of Texas Southwestern Medical Center provides an excellent environment for conducting clinical research.

Environmental Contribution to the Candidate's Success

The physical and intellectual resources available at UTSW Southwestern through the Medical Center, Division of General Pediatrics, Division of General Internal Medicine, the Department of Clinical Sciences, the Taskforce on Obesity Research at UT Southwestern (TORS), and the Center for Human Nutrition will provide with a supportive environment for the completion of the proposed research and for career enhancement. Dr. Glenn Flores, the Director of the Division of General Pediatrics, will be primary mentor. Dr. Debra Roter at the Johns Hopkins School of Public Health, and Dr. Debra Wiebe, Professor in the Department of Psychiatry at UTSW, will be secondary mentors. Sarah Barlow at the Baylor College of Medicine will serve as advisor. This multidisciplinary team of mentors and advisors from the Departments of Pediatrics, Public Health, and Psychiatry will ensure that the candidate has access to faculty and resources in each of these departments, including access to education and training through Dr. Roter at Johns Hopkins.

Several conferences will also provide opportunities for intellectual interactions with other investigators within the Department of Pediatrics, and with other departments at UTSW Southwestern. Weekly Department of Pediatrics grand rounds presentations are given by nationally and internationally recognized leaders in pediatric health research. The Pediatric Departmental Research Conference Series is held weekly, and consists of presentations by researchers in various divisions of the Department of Pediatrics, with in-depth discussions about research design and methodology. It allows young investigators to learn about emerging research, use of qualitative, quantitative, and intervention research methodologies, and receive valuable feedback about their research from a multidisciplinary group of nationally-recognized researchers. attends the Generalist Research in Progress seminar series in the Division of General Pediatrics. These seminars are held twice a month, and provide a venue for senior and junior faculty and fellows in the Division of General Pediatrics to present their on-going research, to obtain feedback on research techniques, and on the relevance of research questions and findings to clinical pediatrics and child health. Under the guidance of Drs. Flores, has presented her research at the Generalist Research in Progress seminar series and at the Departmental Research Conference Series in June 2012.

The Health Services Outcomes Research Seminar Series is hosted by the Division of Internal Medicine. This monthly series consists of presentations of health services research from UTSW and prominent health services researchers from outside the institution, with didactic sessions on advanced health services research techniques. It is led by Dr. Ethan Halm, who is the Director of the Division of Internal Medicine, and an expert in health services research and advanced quantitative analysis methods. presented at this seminar in Spring 2011.

UTSW is home to some of the best investigators and technology for the study of obesity and related metabolic disorders. The Taskforce on Obesity Research at UT Southwestern integrates the traditionally disparate disciplines of lipid metabolism, genetics, clinical epidemiology, intermediary metabolism, and neuroendocrinology into a cohesive center to study the behavioral, metabolic, and molecular mechanisms that cause obesity and the metabolic syndrome. attends the TORS weekly conferences, and has developed relationships with many of the key TORS investigators. The Center for Human Nutrition and the UTSW Southwestern program in Obesity, Diabetes, and Metabolic Research host an outreach program to the medical community, other state institutions, and the general public. The forum is open for discussion of obesity and education programs, and attends these weekly seminars.
March 1, 2013

Center for Scientific Review
National Institutes of Health
6701 Rockledge Drive, MSC 7710
Bethesda, MD 20817

RE: [ ], MD, MHS, NHLBI K23 Grant Application

Dear Review Committee Members,

It is my pleasure to write this letter of support for [ ] in her application for an NHLBI K23 mentored career development award. [ ] has excelled during her time at the University of Texas Southwestern Medical Center (UTSW) and Children's Medical Center. Her career goal is to become a nationally recognized expert on primary care weight-management interventions for overweight children, and she has the ability, focus, and dedication to accomplish this goal.

UTSW is a leading research institution with almost $300 million per year in extramural research support, five Nobel Laureates, 18 faculty in the National Academy of Sciences, and 18 in the Institute of Medicine. There is easy access to resources on campus to provide education and assist with complex projects and there is a strong collegial relationship between departments. [ ] has assembled an outstanding multidisciplinary team of mentors and advisors in the Division of General Pediatrics (Dr. Flores) and Department of Psychiatry and Clinical Sciences (Dr. Wiebe) at UTSW Dr. Roter at the Johns Hopkins Bloomberg School of Public Health and Dr. Barlow at the Baylor College of Medicine Division of Gastroenterology, Hepatology and Nutrition will also serve as advisors for [ ]. She currently has 70% of her time protected for research, with the remaining effort devoted to clinical responsibilities and teaching. As the Chair of the Department of Pediatrics, I will ensure that 75% of her time is protected for research and career development, should she be honored with this award. She has been provided with office space, computer, administrative support, biostatistical support, and all of the resources needed to successfully complete the proposed research.

[ ] is an exceptional young clinical investigator who is ideally suited for the K23 award. We recruited her aggressively because of her excellent training, talent, and outstanding potential for future success as an independent investigator. She has an innovative proposal, an outstanding team of mentors and advisors, a nurturing environment at UT Southwestern, and a department commitment to her success. She has the strongest support from the Department, and she unquestionably will be a highly successful clinician-scientist. I urge the review committee to give her your highest consideration.

Sincerely,

Julio Perez Fontan, M.D.
Professor and Interim Chairman
10. SPECIFIC AIMS

Pediatricians are well-suited to regularly assess and treat school-age children who are overweight; they see over 99% of school-age children regularly for well-child visits, and 75% every six months or less. Evidence suggests that weight-management interventions may be most effective for 6-12 year-old children, and that physician behavior is an important influence on adherence to medical treatment. Thus, well-child visits with school-age children present an important opportunity to assess and treat children who are overweight. Strategies are needed to maximize the effectiveness of this opportunity.

The American Academy of Pediatrics (AAP) endorses recommendations by the United States Preventive Services Task Force (USPSTF) that clinicians screen for overweight, assess medical/behavior risk, use a staged treatment approach that includes frequent reassessment, and communicate using patient-directed techniques to encourage behavior change. It is unclear whether these practices or communication techniques, when used in primary care, impact whether children make lifestyle changes or improve their weight status. It is essential to identify specific clinical practice elements and communication strategies associated with weight-status improvement in overweight children, to maximize the effectiveness of primary-care weight-management interventions.

My long-term goal is to develop an effective, evidence-based, primary-care weight-management intervention to improve the weight status and healthy-lifestyle behaviors of overweight school-age children. The proposed research plan integrates research training activities in quantitative analysis of longitudinal data, RIAS data collection and analysis techniques, survey design to measure constructs of interest, and pilot intervention development and testing to gather preliminary data on the feasibility and acceptability of an intervention to improve pediatricians’ communication and use of specific clinical practice elements when addressing weight and weight management in primary care, with the ultimate goal of designing a future, large-scale randomized, controlled trial examining the effectiveness of an intervention to improve the weight-status and healthy-lifestyle behaviors of overweight school-age children.

Aim 1. Identify specific clinical practice elements in pediatric primary care that predict improvement in weight status among overweight school-age children.

Hypothesis 1: Conducting BMI screening, assessing weight-related comorbidities (including elevated blood pressure, acanthosis nigricans, and elevations in fasting blood glucose, lipids, and liver enzymes), and scheduling one or more interim visits to reassess progress (with a weight-related diagnosis among the top three diagnoses or by referring to a weight-management specialist or nutritionist) in overweight, 6-12 year-old primary care patients will predict improvement in weight status (assessed as decrease in body mass index standard deviation score [ΔBMI z-score]) at one-year follow-up.

Aim 2. Identify communication content and strategies in primary care that predict improvement in weight status among overweight school-age children.

Hypothesis 2a: Pediatrician-patient communication regarding overweight status, behavioral and risk-factor counseling, and interval reassessment, compared with no communication or incomplete communication (about only high weight status without behavioral or risk-factor counseling and/or with no reassessment that occurs prior to the next well-child visit one year later) will predict improvement in weight status (ΔBMI z-score and change in percent over the median percentile of BMI for age and gender [Δ% overweight]) at one-year follow-up.

Hypothesis 2b: During patient-pediatrician communication regarding weight and weight management, higher patient-centeredness will predict improvement in weight status (ΔBMI z-score and Δ% overweight) at one-year follow-up.

Aim 3. Develop and test the feasibility and acceptability of a pilot intervention that is designed to improve weight-status and healthy-lifestyle behaviors through enhancement of pediatricians’ communication skills and use of specific clinical practice elements when addressing weight and weight management in primary care with overweight school-age children.

Hypothesis 3a: The pilot intervention will improve pediatricians’ use and competence in using specific clinical practice elements and effective communication when addressing overweight during primary care visits, as measured by video-recording and self-report, compared with a control group of pediatricians using standard practice behavior.

Hypothesis 3b: The pilot intervention will be feasible and acceptable for pediatricians and patients and parents. Feasibility will be determined by adherence to the study protocol by providers, attractiveness of the intervention, user-friendliness, comprehensibility, and perceived effectiveness by providers and patient families. Acceptability will be determined by conducting focused in-depth interviews of pediatricians and participants using semi-structured, open-ended questions.
11. RESEARCH STRATEGY

A. Significance. Overweight (OW), including obesity, is one of the most pervasive and costly public-health problems in the US. Current estimates indicate that one in three children is OW.1 Pediatricians now care for children with obesity-related metabolic disorders, including dyslipidemia,4 hypertension,4 and prediabetes/diabetes.5,7 In fact, over 60% of OW school-age children have at least one cardiovascular disease (CVD) risk factor.2,4 This suggests that we may be experiencing only a small portion of a much larger problem of obesity-related CVD that will dwarf current estimates of the lifetime risk of CVD morbidity and premature death, risks which can be reduced in children who attain healthy adult weights.8,10

Well-child visits for school-age children are an important opportunity to assess and treat childhood OW. Over 99% of school-age children are seen regularly for well-child visits.10 Furthermore, evidence suggests that weight-management interventions may be most effective for 6-12 year-old children,11,12 and that pediatrician behavior impacts adherence to treatment advice.13 Thus, pediatricians are well-suited to regularly assess and treat school-age children who are OW.

B. Innovation. Little is known about strategies that pediatricians are using that translate into children attaining healthier relative weights and improved cardiometabolic risk.14,15 The AAP and USPSTF recommend that clinicians screen for OW, assess medical/behavior risk, and use a staged treatment approach (Fig. 1).18 Thus, pediatricians have a wide array of childhood OW assessment and treatment options.16-18 Pediatricians often order screening labs and discuss the results, hoping to cue action by indicating that the child has CVD risk factors, and structured weight management may be prescribed. It is unclear whether these practices or the manner in which pediatricians communicate with patients have an impact on whether children make lifestyle changes or improve their weight. It is anticipated that the proposed research will identify specific clinical practice elements and pediatric-patient communication strategies that are associated with successful weight improvement in OW children.

The proposed research will be a significant contribution because it will provide a data-driven evidence base for effective weight-management assessment, treatment, and communication strategies in primary care for OW children. Clinical experiments have identified a limited set of behavioral interventions "suitable for use in pediatric primary care" that improve weight when practiced by the patient.11,12 A few studies have also examined the impact of specific communication strategies used by pediatricians for eliciting patient behavior change, such as motivational interviewing (MI); although MI is based on a sound theoretical framework, its use has not reliably helped OW children improve their weight.19-21 Little is known about clinical practice and communication strategies that pediatricians already are employing which translate into children attaining healthier relative weights and improved cardiometabolic risk. The goal of the proposed research is to identify specific clinical practice elements and communication strategies in primary care that are effective in improving weight status among OW children. The proposed research is innovative because it will identify, for the first time, evidence-based clinical practices that pediatricians can use to help their patients improve their weight, and because it will determine which specific communication strategies result in weight-status improvement.

C. Approach.

1. Literature Review. Although major issues loom about the role of public policy, media, and corporate responsibility in creating an environment that facilitates weight management, pediatricians care for OW children in their practices right now, and need evidence-based guidance on how to maximize the effectiveness of this opportunity to help OW children manage their weight.22 Because weight management is a lifelong process, self-determination theory is an ideal theoretical model to guide pediatricians in assisting OW children with weight management (Fig. 2).23 According to self-determination theory, for individuals to adopt weight-management-related goals, they need to feel not only competent at task-oriented behaviors, but also autonomous in choosing behaviors and achieving goals.23 In other words, pediatricians may be maximally effective in helping patients manage their weight if they can activate patients' own intrinsic motivations, such as for health and personal growth, instead of placing extrinsic pressure on patients to do what they should or must to avoid negative consequences. When a child is the patient, though, change frequently depends on the child's
As such, the pediatrician may advocate for the child's health by activating the parent's intrinsic motivation for changing the home environment to support the child's ability to self-regulate intake and access activity opportunities. Promoting high-quality intrinsic motivation, according to self-determination theory, could stimulate self-sustained successful weight management, and help design more effective interventions. 29,30

Patient-centered communication is a consultation method that supports patient autonomy and activation of patients' intrinsic motivation. 31-33 MI is one type of patient-centered communication that is used to promote behavior change, but physicians can use patient-centered communication without using MI. 34 Patient-centered communication elicits patient's health needs, beliefs, and expectations; engages patients in the decision-making process of their care by eliciting their input and conveying information that is understandable and empowering; and builds trust, relationships, and partnerships between patients and physicians. Patient-centered communication has been shown to promote adherence. 35,36

To discuss weight management, patients (and their parents) first must recognize that they are OW, and body mass index (BMI) screening increases parental recognition that their child is OW. 37,38 This is important because about 60% of parents do not recognize that their school-age child is OW. 39 Pediatricians are encouraged to screen for OW (defined as a BMI ≥ 85th percentile) in children ≥ 6 years old, and to offer or refer children for moderate-to-high intensity interventions that include diet, activity, and behavioral counseling components. 15,39 Studies indicate, however, that only half of pediatricians perform BMI screening. 40-42 Many studies, 43 including the PI's, 44 suggest that OW children and their parents desire and expect primary-care guidance regarding OW, related health-risks, and behaviors that help improve the child's weight. It is unknown, however, whether BMI screening and offering or referring children for more intensive interventions during routine primary care impacts outcomes such as weight-status improvement and adoption of healthy behaviors.

The frequency and intensity of follow-up in primary care that are needed to promote successful weight improvement in OW children also are unclear. The recommendation to pediatricians to screen for OW states that no evidence exists to support an appropriate screening interval. 39 Experimental studies of primary care weight-management interventions suggest that more frequent, higher-intensity behavioral counseling sessions result in small-to-moderate improvements in BMI. 17 It is unknown whether more frequent primary-care visits that address OW, or referral for more intensive intervention (by a nutritionist or weight-management program) leads to similar improvements in weight status.

Although much research has focused on patient practices that promote weight-management success, the proposed research seeks to identify and prospectively test specific pediatrician practice elements and communication strategies that promote successful weight improvement in OW children. Patient-centered communication regarding BMI screening, CVD risk-factor-assessment results, and behavioral counseling may activate patients by helping the parent/patient identify the child's OW status, the risk and/or presence of weight-related diseases, and specific behaviors that can empower the patient to actualize a healthy future. Identifying effective clinical practice elements and communication strategies will maximize the likelihood that children embrace healthy behaviors that promote lifelong weight-management long after a child outgrows their pediatrician. The proposed research will contribute novel information regarding specific clinical practices and communication strategies that improve outcomes, such as weight status and health practices, and process measures, such as patient-centered communication.

2. Preliminary Studies. The PI has conducted preliminary studies which provide a solid foundation for the proposed K23 research. Using a nationally-representative dataset of children, she documented that, compared with healthy-weight children, OW children had significantly greater adjusted odds of suboptimal health and emotional/behavioral problems, and that these problems were associated with greater healthcare expenditures among OW children. 45 These findings highlight the need for strategies to help pediatricians maximize the effectiveness of opportunities to assess/treat OW children in primary care. The PI used focus groups to identify parental expectations regarding weight-management strategies for their OW children, including the role of their child's pediatrician. 44 This study revealed that parental expectations for the pediatrician include communicating
Directly regarding their child's OW status, both assessing and providing guidance regarding healthful diet and activity behaviors, screening and informing parents of health risks, and providing consistent follow-up. The PI surveyed pediatricians regarding their competence in using clinical practice elements recommended by parents in her focus-group study and by the AAP. Data from the surveys suggest that most pediatricians report being very competent/competent in identifying OW (93%), related conditions (73%), and arranging follow-up (73%), but lower competence in treating weight-related conditions (47%) or counseling regarding a "healthy diet" (53%), physical activity (60%), or media/screen use (67%). The PI also video-recorded primary-care visits to examine how pediatricians and OW patients/parents communicate regarding weight. Data from this study indicate that 93% of pediatricians communicate children's high weight status, but only 40% assess and 20% counsel OW patients regarding the AAP-recommended "5-2-1-0" behaviors, which include eat five fruits/vegetables daily, limit screen time to ≤2 hours/day, be physically active ≥1 hour/day, and no sugar-sweetened drinks. In this study, communication regarding mental/behavioral health occurred in 42% of visits, and of weight-related health risks in 54%; lab assessments were discussed or ordered in 73%, 65% of pediatricians scheduled follow-up (at intervals of 1-3 months), and when follow-up was not scheduled, nutrition referrals were made by 80%. This study suggests that pediatricians identify OW and schedule follow-up, but report less competence and perform behavioral counseling less frequently than other recommended clinical practice elements. In another study, the PI used baseline data from OW mothers and high-risk children in a weight-control intervention to determine the proportions who met the AAP-recommended 5-2-1-0 behavior goals. She found that few children or mothers met behavior goals, meeting more goals was associated with a lower likelihood of maternal obesity, and children had a higher likelihood of meeting a behavior goal when mothers met the corresponding goal. In Aims 1-3, the PI will evaluate whether findings from these preliminary studies translate into weight-status improvement, including: using weight-management strategies parents expect, and therefore may be more likely to adhere to; discussing a child's high weight status; recommending 5-2-1-0 behaviors; obtaining/discussing laboratory studies; increasing the frequency of visits; and referring OW children to nutrition or weight-management programs.

D-F. Research Plan: D.1. Aim 1. Identify specific clinical practice elements in pediatric primary care that predict improvement in weight status among OW children. It is hypothesized that engaging the patient in BMI screening, assessment of weight-related conditions (for example, elevated blood pressure [BP]), and reassessment (completing ≥1 follow-up visits in which weight is assessed or referral to a nutritionist/weight-management program) in OW primary-care patients will predict improvement in weight (assessed as BMI standard deviation score change [ΔBMI z-score]) at 1-year follow-up. Factors identified in this aim will eliminate an essential gap in knowledge about specific clinical practice elements that predict improvement in weight status of OW children, including whether identifying weight-related CVD risk factors and conveying the results predicts improvement in weight. Completion of Aim 1 will allow the development of evidence-based intervention components which may aid pediatricians in helping patients attain healthier weights.

2. Preliminary data. Based on preliminary analysis of internal data in the Children's Medical Center Dallas (CMC) EPIC electronic medical record (EMR), 26,313 6-12 year-old children have been seen at least twice in CMC-affiliated primary-care clinics. Of the 12,341 (47%) who are OW (BMI-percentile [BMI%] ≥85th), 6,356 (52%) decreased their BMI% between the first and last visit.

3. Research design/Protocol. A nested case-control study design will be used (Fig. 3). A random sample of controls will be matched to cases by age, gender, race/ethnicity, BMI% category (OW, obese, or severely obese [BMI% ≥85th -95th, ≥95th -99th, and ≥99th, respectively), and clinic site.

4. Data Source. CMC is the seventh largest pediatric hospital in the nation. The cohort for this case-control study will include children seen in CMC's seven primary-care clinics, covering a 30-mile radius of Dallas, including one hospital-based clinic and six community clinics. The sociodemographic composition of the patients is similar to the 654,000 children ≤18 years old residing in Dallas County, with slightly more Latino children (60% at CMC vs. 51% in Dallas County), and an equivalent number of African-American children.
(25-30% at CMC vs. 25% in Dallas County). Primary-care data will be obtained from the CMC Hospital Data Center. CMC has used an EPIC-based EMR system since 2009. The dataset will include children with ≥2 visits, a BMI ≥85th%, and 6-12 years old at the first visit.

5. Outcome. Cases are defined as children with a decrease in BMI z-score over 12-months between the first and last recorded visits that have valid height and weight data. Controls are defined as children whose BMI z-score remained unchanged or increased. BMI z-scores will be defined using age- and gender-specific Center for Disease Control (CDC) growth-chart z-scores. Weight and height are measured directly by nurses according to standardized clinical protocols using standardized scales and wall-mounted stadiometers.

6. Predictors. Patient characteristics to be examined include age, gender, race/ethnicity, insurance type, physical/mental health conditions, new medications, and clinic site. Variables used to assess clinical practice elements are detailed in Fig. 3, and include three variables indicating that the provider 1) identified OW; 2) assessed; or 3) reassessed the child’s OW status. An assessment also will be performed regarding whether completed referrals and labs (not the act of ordering them) are associated with weight-status improvement. Ordering a referral that is not completed will be treated as evidence that the pediatrician identified OW but did not complete the assessment—this differentiation is important, because to change health outcomes according to self-determination theory (Fig. 2), the physician must engage the patient in the assessment process.

7. Analysis. Bivariate associations will be examined, and variables significantly associated with the outcome included in a multilevel model. Using a multivariable logistic regression model to predict the outcome would fail to recognize the clustering of patients within the seven CMC clinics. Multilevel modeling techniques will be used to stratify and adjust for clustering at the clinic level, thereby providing more accurate estimates of the individual-level effects. We will stratify ΔBMI z-score improvement 1) by tertiles, and 2) by ΔBMI z-score ≥0.25 and >0.5 (recognizing that ΔBMI z-score of 0.25-0.5 has been associated with reduction in CVD risk factors) to examine the impact of effective clinical practices on different categories of the magnitude of BMI z-score improvement. Odds ratios and 95% confidence intervals will be used to examine associations between predictors and the outcome. P-values will be 2-sided, with a P<.05 considered statistically significant.

8. Sample Size. The sample size needed for a binary outcome depends on the prevalence of the outcome in the population. A preliminary analysis suggests that, of the 12,341 OW 6-12 year-old children followed in CMC clinics, the prevalence of any weight-status improvement is 52% (N=6,356), of ≥0.25-point decrease in BMI z-score is 14% (N=1,678), and ≥0.5-point decrease in BMI z-score is 3.5% (N=432). These sample sizes provide >90% power to detect effect sizes of ≥5-10 percentage points for the outcome, adjusting for clustering.

9. Potential problems/alternative strategies. It is possible that no specific clinical practice elements predict weight-status improvement. This would be an important finding—if, for example, screening and communicating results of CVD risk factors have no relationship to improvement in weight status, and the current strategy for treating these risk factors is recommending weight loss, then pediatricians may need to be more aggressive about using potent dietary interventions or starting medications to treat persistent conditions, including hypertension, to prevent hard outcomes such as myocardial infarction or stroke. A retrospective case-control study has the possible disadvantage of producing groups that might contain inherent biases. To address this, cases will be matched to controls on key demographic characteristics, and alternative hypotheses may be tested. Severity of OW, health or behavioral conditions, and medications, for example, may have a greater effect on weight than pediatrician clinical practices. One of the PI’s preliminary studies found that OW was associated with suboptimal health and behavior problems; these are valid alternative hypotheses.

E.1. **Aim 2.** Determine communication content and strategies in primary care that predict improvement in weight status among OW children. There is little information on pediatrician-patient communication content and strategies that improve outcomes, including weight status, process measures such as increased parent satisfaction with care and partnership with the pediatrician, and pediatric practice elements (including CVD risk-factor assessment and the optimal follow-up interval). We hypothesize (Aim 2a) that pediatrician-patient communication regarding OW status, behavior/risk-factor counseling, and the frequency and time to next follow-up visit, compared with either no communication or incomplete communication (communicating only high weight status without behavior/risk-factor counseling or a follow-up visit) will predict improvement in weight status at one year follow-up, and that during pediatrician-patient communication regarding weight and weight management, higher patient-centeredness will predict improvement in weight status at one year follow-up (Aim 2b). The communication content identified in **Aim 2** will generate novel information about the most effective content and style of pediatrician-patient communication that predict weight-status improvement. Because we prospectively will examine clinical practice elements in the one-year interval between well-child visits, acknowledging that communication regarding high weight status may initiate CVD risk factor assessment, more frequent follow-up visits, or prompt a nutrition referral, we will generate novel information...
about the most effective clinical practices and follow-up interval and frequency that predict weight-status improvement in OW children. We also will examine if the content and style of communication are related to improvements in 5-2-1-0 behaviors at one-year follow-up (see App. 1 for 5-2-1-0 measures and validity). Although specific communication content may change short-term behavior, the reason to assess change in behavior at one-year follow-up is to capture self-sustained autonomous behavior change. Completion of this aim will allow development of evidence-based intervention components informed by communication and clinical-practice strategies which may aid pediatricians in delivering effective weight-management care.

2. Research design and protocol. In this prospective, observational study, we will recruit pediatricians and inform them that this study will examine the relationship between communication regarding preventive-health topics, patient adherence, and healthcare use, not that the study will examine conversations about weight, to minimize the Hawthorne effect (the possibility that pediatricians and patients might change their behavior due to being observed). We will video-record well-child visits for 85 OW 6-12-year-old patients and their pediatricians, and then prospectively collect data (using EMRs) on weights/heights, diagnoses, medications, time to first follow-up for OW/obesity, and the number, frequency, content, and nature of follow-up visits, and finally re-measure children at the next well-child visit, one year later (Fig. 4). At the end of the study, pediatricians and participants will be debriefed regarding the specific aims of the study. We will use Roter Interaction Analysis System (RIAS) methodology to code the dialogue, and to determine patient centeredness. RIAS is a widely used method for analyzing medical dialogue for physician-patient communication quality and content that has been shown to be reliable and valid. RIAS was chosen because it can be used to elaborate on specific kinds of exchanges, including BMI/lifestyle counseling; multiple speakers can be coded to distinguish parent from child: it is practical, because no transcription is required; and it is applicable to visits conducted in other languages, including Spanish.

3. Recruitment. Recruitment sites will include academic, community, and private-practice pediatric clinics. Clinic directors already have provided initial agreements to participate (see Letters of Support and Facilities for practice priorities and pediatrician/patient characteristics). All participating physicians at each clinic will be asked to participate (33 eligible), and 25-30 patient encounters/clinic will be randomly recorded. At the academic clinic, only residents will be eligible. The reason for the focus on residents is that they see an individual patient for every appointment, whereas attending physicians can be different for each appointment. At the community and private practices, pediatricians that spend ≥20 hours/week providing outpatient care will be eligible. Pediatricians will be e-mailed an invitation to participate (see App. 2), and clinics visited to obtain informed consent. Patient eligibility criteria are outlined in Table 1. To identify potential participants, scheduled patient visits will be reviewed (under a HIPAA waiver). Participants will be recruited sequentially prior to the visit. The PI and research assistant will inform the patient/parent about the study and obtain informed parent consent/child assent (see App. 2). The number of eligible candidates/week for the PI's related study was 10-15 at the community clinic and 3-5 at the academic clinic.

4. Data collection. To examine the impact of pediatrician-patient congruency in gender, race/ethnicity, and language, pediatricians will complete a 10-minute survey assessing these characteristics. The survey also will contain questions about pediatrician self-efficacy in discussing weight management (see App. 3). Pediatricians will be paid a $25 participation honorarium. Child BMI will be determined using measured weights/heights (collected according to each clinic's standardized protocol) at the index visit, during all follow-up visits, and at the next well-child visit, one year later. To examine pediatrician-patient communication content, well-child visits will be video-recorded with two small wall-mounted video cameras placed unobtrusively in the exam room; concealing cameras is a published approach to help minimize reactivity to being videotaped that the PI used in her related communication study. Following the visit, the parent will complete surveys assessing child/family demographics (see App. 2), health status, parent/child perceptions of weight, and pediatrician participatory-decision-making (PDM) style, which has been
linked to continuity of care over time and patient satisfaction. Health behaviors in the child will be assessed at each well-child visit and include the 5-2-1-0 behaviors that pediatricians are encouraged to assess and counsel children on (See App. 1). Autonomous versus controlled regulation of these health behaviors will be measured with the Self-Regulation Questionnaire (SRQ). Participants will receive a $25 honorarium for each completed survey. At 4-month intervals during the year between well-child visits, follow-up visits (and follow-up-visit frequency), weights/heights, diagnoses, medicines, labs, and referrals will be tracked in EMRs.

5. Outcomes. The primary outcomes will be ΔBMI z-score and change in percent OW (Δ%OW), defined as the percent over the median BMI percentile for age and gender) at 12 months. The reason for using both outcomes is that ΔBMI z-score of 0.25-0.5 has been associated with reductions in CVD risk factors, whereas Δ%OW changes comparably for similar weight changes in OW and severely-obese children. In contrast, an OW child would have to lose substantially less weight than a severely-obese child for the same ΔBMI z-score. Using both measures will allow examination of the relationship between relative weight changes and CVD risk-factor improvement. Secondary outcomes include parental report of change in the number of “5-2-1-0” behavior-goals met, change in self-determined versus controlled regulation of these health behaviors, and improved child health status (using items from the National Survey of Children’s Health).

6. Predictors. Pediatrician-patient communication regarding OW, behavior and CVD risk-factor counseling, and patient-centeredness will be determined through communication analysis. Interval weights/heights, physical/mental-health conditions, lab assessments, follow-up-visit frequency, and referrals will be determined by EMR review. Content-specific communication regarding OW, weight-related conditions, and diet and activity assessment/counseling will be identified. Patient-centeredness will be scored as the ratio of patient to doctor-centered communication regarding weight topics. Means will be calculated for total and weight-communication-specific pediatrician, child, and parent-talk time, and patient, doctor, and the ratio of patient/docotor-centered communication scores (Fig. 5). For the primary hypothesis, biomedical information-giving (for example, risk-factor communication) will be treated as patient-centered because the PI’s focus groups suggest that parents want this information, and prior research suggests that including biomedical-information giving improves the correlation of Roter’s patient-centeredness measure with patient health status and satisfaction scores.

Surveys will be used to assess parent-reported pediatrician participatory-decision-making style and perception of involvement in care, which will be determined using five questions from the Healthcare Climate Questionnaire (modified by one of the PI’s mentors, Dr. Weibe, for use with children). Videotapes will be reviewed by coders unaware of study hypotheses. Using the RIAS framework, coders will classify speaker’s utterances into four main content areas: data gathering, education/counseling, responding to patient emotions, and partnership building. Coders will rate the affect of speakers across several dimensions, using scales of 1-6 (1=low, 6=high). Reliability will be determined from a random sample of 10 visits, and interrater correlation (Spearman r) will be calculated for child, parent, and pediatrician talk.

7. Sample size. The minimum detectable difference chosen for ΔBMI z-score is ±0.375 (midpoint of the range associated with CVD risk-factor reduction), and for Δ%OW is 10%. Power calculations were performed using STATA, a power of 80%, and a two-tailed P≤0.05. Because there does not appear to be a prior study associating BMI screening with relative weight change, SDs were derived from an intervention study using these SDs, 12-46 patients are needed to detect a minimum difference in ΔBMI z-score of 0.375, and of Δ%OW of 10%. Prior research indicates, however, that only 50-80% of visits address weight. Therefore, we plan to enroll 85 participants, including 10 participants for validation of RIAS coding, adjusting for clustering, and assuming 10% attrition. Internal data for the academic clinic suggests <10% attrition for well-child visits.

8. Data analysis and interpretation. Bivariate associations between independent and dependent variables will be examined for the primary and secondary outcomes. Mixed-effects models will be used to test hypotheses, which will implicitly account for correlation due to clustering within and between pediatricians and clinics, and will incorporate all measurements of weight/height (including at interval visits and referrals). The Hypothesis 2a model for a child, c, clustered with a pediatrician, p, within clinic-site s can be written as, $Y_{cps} = \beta_0 + \beta_1(discussed) + b_0 + b_1(s CPS) + c_{cps}$, where $Y_{cps}$ is ΔBMI z-score/Δ%OW from baseline to one year; $\beta_0$ equals Δweight status for a child when a pediatrician does not communicate regarding OW status, counsel, or schedule reassessment (discussed=0); and $\beta_1$ is the coefficient multiplied by 1 if the pediatrician directly

Research Strategy
communicated or counseled, by 2 if communication and counseling occurred, and by 3 if communication, counseling, and reassessment occurred. The impact on weight-status improvement of interval-lab-assessment communication, interval follow-up (and the optimal interval of follow-up), and referrals also will be explored. The variables $b_1$ and $b_2$ indicate random effects/variability due to patients being nested within pediatricians and clinics; $e_{cep}$ is an error term. The null hypothesis will be rejected if $b_1$ is significantly <0. The Hypothesis 2b model will test whether higher patient-centeredness scores during the baseline visit are associated with weight improvement between baseline and one year, and will include an additional coefficient, $b_2^2$(patient-centeredness score), where $b_2$ is the coefficient multiplied by the patient-centeredness score. The null hypothesis will be rejected if $b_2$ is significantly <0.

9. Potential problems and alternative strategies. To minimize the possibility of the Hawthorne effect for study pediatricians and patients, participants will be masked to the study aims. In accordance with prior videorecording studies and our pilot study, small videocameras will be wall-mounted unobtrusively in the exam room.\footnote{62} Another method to limit reactivity to being videotaped is to discard each pediatrician’s first recorded visit.\footnote{62} Analyses of repeated visits in the PI’s pilot study, however, suggest that pediatrician’s communication content and practices did not vary from the first to the last visit. Another possible challenge is that there likely will be differences in communication and practice between clinics and providers. To address this, we will explore how recommended guidelines are implemented in the various practices and diverse populations, and examine the impact of pediatrician-patient congruency in weight status, gender, race/ethnicity, and primary language on the relationships between patient-centeredness, communication content, and outcomes, and control for clinical practice elements that are significantly related to outcomes in bivariate analyses.

F.1. Aim 3. Develop and test the feasibility and acceptability of a pilot intervention aimed at improving pediatricians’ use of specific clinical practice elements and communication content when addressing weight and weight management in primary care with OW school-age children. Evidence from weight-management efficacy trials has documented that weight improvement is achievable for certain patients.\footnote{11-12} In primary care, however, evidence is limited on how to help OW children improve their weight. The goals of the Aims 1 and 2 studies are to create an evidence base for clinical practices and communication strategies that pediatricians can use to help their patients improve their weight. The focus of the Aim 3 study will be to develop a pilot intervention derived from the Aims 1 and 2 study findings and test the feasibility and acceptability of the clinical-practice and communication-strategy components, in routine clinical practice. Previously published key concepts that should be examined in feasibility studies include: acceptability (perceived appropriateness), implementation (degree of execution), and limited-efficacy testing (with intermediate outcomes or limited statistical power).\footnote{61} Pilot study findings will be used to develop a larger study designed to improve the weight-status and healthy lifestyle behaviors of overweight school-age children through enhancement of pediatricians' communication skills and use of specific clinical practice elements when addressing weight and weight management in primary care, for which the PI will seek R01 funding in the 5th year of the Award.

2. Research Design. A randomized, controlled pilot trial will be used to test the feasibility and acceptability of a four-month intervention that will train and support pediatricians in employing the clinical practice elements and effective communication strategies, identified in the Aims 1 and 2 studies, in routine clinical practice. The study will use video-recording of primary-care visits, self-administered acceptability and feasibility questionnaires (based on published feasibility guidelines), and brief interviews to determine outcomes. The primary outcome will be pediatricians’ use of and self-reported competence in using the effective clinical practice elements and communication strategies. Secondary outcomes will include the feasibility and acceptability of the interventions to pediatricians and parents. The impact on improvement in weight status of the interventions' clinical-practice and communication-strategy components will be explored. We envision that the interventions will include implementation of point-of-care practice support to aid pediatricians in using the specific clinical practice elements and a communication-skills training, using on-line training modules and audit and feedback to providers, which has been shown to improve professional practice and healthcare outcomes.\footnote{62} Pediatricians and patients/parents will complete surveys at the beginning and end of the four-month intervention.

3. Population/recruitment sites. 30 pediatricians and 60 8-12 year-old OW children will be recruited from primary-care practices, using the same eligibility criteria for pediatricians/patient-participants as those in Aim 2. We will recruit pediatricians in the Dallas area from among academic, community, and private practice sites.

4. Protocol/Randomization. Pediatricians will be randomly assigned to the intervention or standard practice. To determine whether pediatricians are using the effective clinical practice elements and communication strategies, we will video-record communication with two patients per pediatrician during well-child visits, one at baseline and one after intervention pediatricians receive training and control pediatricians receive printed copies of the AAP recommendations regarding the assessment and treatment of OW/obesity.\footnote{16}
will be asked to give written and verbal assessments of the feasibility and acceptability of each component of the intervention (the clinical practice elements and communication strategies) following the feedback session and at the study's end. Patient participants with follow-up visits in the study period will have the follow-up weight/height recorded, through EMR review. Participants will receive a $25 honorarium/recorded visit.

5. **Intervention**: Pediatricians randomized to the intervention will receive training on communication skills and clinical practice elements that promote successful weight management among school-age children. Although the specific intervention elements are subject to change, intervention pediatricians will watch a 15-minute online module detailing the effective clinical practice elements that promote successful weight management among school-age children and three 15-minute modules on effective pediatrician-patient communication regarding weight management. For example, if the Aims 1 and 2 studies suggest that BMI and risk factor screening and communication, a 1-month follow-up visit (the optimal follow-up frequency determined from the Aims 1 and 2 studies will be used to recommend a follow-up interval), and patient-centered communication strategies must be applied to promote weight-status improvement, then the intervention might include training in the use of point-of-care practice supports to automate the identification of OW patients, to recommend CVD risk factor assessment and treatment, and to prompt the pediatrician to arrange 1-month follow-up, and a communication-skills training, for example, on reflective listening, eliciting patient preferences, and incorporating patient preferences and medical evidence into a clear and specific weight-management plan. Then, intervention pediatricians will receive written and verbal feedback regarding their use of the clinical practice elements and communication strategies, which will be determined by reviewing baseline videotapes. Control group: Controls will receive copies of the AAP recommendations, continue their current weight-management practices, be videotaped, and sessions analyzed identically to the intervention-group sessions.

6. **Outcome measures**. The primary outcome, use of the communication strategies and clinical practice elements, will be determined by reviewing video-recorded primary care visits, and coding the communication content for patient-centeredness, and specific assessment/counseling/reassessment content (See App. 3 for an example of data from the PI's preliminary study). For the secondary outcomes, pediatricians' self-reported competence will be assessed using a five-point Likert scale (see App. 2). Patient/parent's self-reported pediatrician participatory-decision-making style will be elicited in the same fashion as in Aim 2. Feasibility and acceptability will be determined using acceptability and feasibility questionnaires and by conducting focused in-depth interviews of pediatricians and patient-participants, using semi-structured, open-ended questions.

7. **Analyses**. To compare rates of use of the clinical practice elements and communication strategies between baseline and four months, we will fit logistic regression models, and use multi-level modeling (performed using STATA) to stratify by OW/obese and account for clustering at the clinic and pediatrician levels. A two-sided *P* < .05 will be considered statistically significant. **Sample Size**. Prior literature suggests that ≤5% of pediatricians use all currently recommended practices for assessing and treating OW. Using a two-tailed *P* < .05, enrolling 30 pediatricians would provide >80% power to detect at least a 25% difference between trained and untrained pediatricians in use of specific effective clinical practices and communication strategies.

9. **Potential challenges/alternative strategies**. The pilot study will not be powered to assess if use of the clinical practice elements and communication strategies results in weight-status improvement when tested prospectively. To address this, we will explore the impact of the intervention components on effective clinical practice elements (and on improvement in patient weight status for children with interim visits in the study time period) in a similar manner as in Aim 1, through analysis of EMR data.

**G. Time Line**. The time line for the proposed five-year award is as follows:

<table>
<thead>
<tr>
<th>AIM</th>
<th>TASK</th>
<th>Year 1</th>
<th>Year 2</th>
<th>Year 3</th>
<th>Year 4</th>
<th>Year 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Extract CMC electronic medical record data</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Clean data, perform descriptive and multilevel modeling analyses</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Recruit pediatricians, participants, record visits, and collect baseline data</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Code recordings and determine inter-rater reliability</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Present findings, write/submit manuscript on clinical practice elements</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Collect one-year follow-up data, and clean and analyze data</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Present findings, write/submit manuscript on one-year data</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Recruit clinics, pilot intervention, and collect, clean, and analyze data</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Present findings, write/submit manuscript on pilot intervention</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>R01</td>
<td>Develop effectiveness intervention trial (grant application)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**H. Next steps**. The Aim 3 pilot-study findings will be used as preliminary data for an R01 application (in Year 5 of the proposed award) for a large-scale RCT examining the effectiveness of an intervention to improve pediatricians’ communication and use of specific clinical practice elements when addressing weight and weight management in primary care with OW school-age children.
14. PROTECTION OF HUMAN SUBJECTS

The proposed studies qualify as non-exempt human-subjects research. The Aims 1 and 2 studies do not fulfill the criteria for a clinical trial. The Aim 3 study will be a pilot randomized, controlled trial of a pediatrician educational intervention; there will be no administration or evaluation of any medication or medical device as part of the research protocol. Prior approval to conduct all research will be obtained from the University of Texas Southwestern Medical Center Institutional Review Board (IRB).

A. Risks to Human Subjects

1. Human Subjects Involvement, Characteristics, and Design

The Aims 1, 2, and 3 studies will examine pediatrician’s clinical-practice elements and communication strategies, and their impact on 6-12 year-old overweight children’s relative weight (BMI z-score). The rationale for studying pediatricians is that their behavior impacts patient adherence to treatment advice, and they use (or are recommended to use) a wide array of childhood overweight assessment and treatment clinical-practice and communication strategies (outlined in Fig. 1) that may improve the chance that an overweight child’s weight status improves; however, the impact of these strategies on child weight-status improvement has not been tested. The rationale for enrolling children, and specifically focusing on 6-12 year-old overweight children followed in primary care, is that in this age range 1) over 99% of children are seen regularly for well-child visits, 2) over 60% of overweight children have at least one CVD risk factor, and 3) weight-management interventions may be most effective for these children, and 4) weight-status improvement by adulthood reduces the lifetime risk of CVD morbidity and premature death.

Aim 1

In Aim 1, a nested case-control study will be conducted to examine clinical practice elements in primary care associated with weight-status improvement in 6-12 year-old overweight children. A case-control study is preferable because a low prevalence of weight-status improvement is expected. Studies indicate that among school-age children followed for one year, only 9% improve their BMI z-score by 0.25 points, and 1% by 0.67 (one centile on the growth chart). Existing electronic medical record (EMR) data will be used, and no further enrollment will take place. The same population of children followed in CMC primary-care clinics will be used to select cases and controls (Fig. 6). The final dataset will include 6-12 year-old children with ≥2 visits, valid height and weight data at each visit, and a BMI ≥85th % at the first visit. The study will exclude children with a BMI <85th % at the first visit, and without valid weight and height measures at two visits within the study period. Cases and controls will be selected to reflect the proportions of racial/ethnic minority children followed in the CMC primary-care clinics (60% Latino, 30% African-American, and 10% Caucasian), with equal gender distribution.

Aims 2 and 3

In the Aims 2 and 3 studies, we will recruit pediatricians, children, and a consenting parent, and eligibility criteria will be the same for both studies. Pediatricians and children will be selected to reflect the proportions of minority pediatricians and children in the practices (see Facilities section for characteristics of pediatricians and patients at each practice).

In Aim 2, pediatricians and participants will be informed by trained study personnel that the purpose of the study is to observe how pediatricians and patients discuss preventive health topics during well-child visits to improve delivery of health services to patients. Not that the study is about weight or weight-management—in this regard, both pediatricians and participants will be blinded to the study aims. The rationale for not informing participants about the study’s specific focus (conversations about weight) is that the goal is to observe what typically occurs between pediatricians and families in conversations regarding overweight in children, and so every effort will be made to avoid influencing or biasing such conversations. At the end of the study, pediatricians and participants will be debriefed regarding the specific aims of the study.
All pediatricians at each clinic will be invited to participate (see Appendix 2). More pediatricians will be recruited (provide informed consent and baseline survey data) than recorded, because in order to review a pediatrician's patient schedule, they must first agree to participate, and not all recruited pediatricians will have eligible patients, or patients that agree to participate. We anticipate that approximately 15 pediatricians will be recruited and recorded from three practices (five per site; Fig. 7). Pediatricians at the community and private practices will be eligible to participate if they provide outpatient pediatric care ≥20 hours/week. Based upon this criterion, there are 19 eligible pediatricians, the gender distribution is about equal, seven speak Spanish fluently, and there are four minority pediatricians. At the academic clinic, only second and third-year residents will be eligible (N=28). As described in the Research Strategy, the reason for the focus on senior residents is that they see an individual patient for every appointment, whereas the attending physician can be different for each appointment. Twenty-eight residents follow patients in the CMC Continuity Clinic, and (of the classes that would be recruited) over one-third are minority pediatricians (three Latino, three African-American, and four Asian). Eighty-five children and a consenting parent will be recruited. Patients will be eligible for the study if they schedule a well-child visit with a participating pediatrician, agree to participate, and record their visit (Fig. 7). Pediatricians will be given a $25 honorarium after their first recorded visit.

In Aim 3, a randomized, controlled pilot trial will be used to test the feasibility and acceptability of a four-month pilot intervention that will train and support pediatricians in applying the clinical practice elements and effective communication strategies (identified in the Aims 1 and 2 studies) in routine medical practice. Recruitment will occur in pediatric primary-care practices in the Dallas area. To be eligible to participate, pediatricians must practice at clinics that use an EMR. To enhance generalizability, pediatricians will be recruited from academic, community, and private-practice sites. Participants will consist of 30 pediatricians, 60-12 year-old overweight children, and a consenting parent/legal guardian. Eligibility criteria for pediatricians and patient-participants will be identical to those in Aim 2. Pediatrician eligibility will be assessed by survey. Pediatricians in both the intervention and control groups will be given a $50 honorarium after completion of the study. To ensure balanced allocation of pediatricians from academic, community, and private-practice sites to the intervention and control groups, the study statistician will perform permuted-block randomization with a block size of three and an allocation ratio of 1:1. The rationale for specifying a communication-skills training for the Aim 3 intervention was to translate findings from the Aims 1 and 2 studies into an intervention. Ultimately, the final intervention components will be informed by results from the Aims 1 and 2 studies.

2. Sources of Materials.

No specimens will be obtained from any subject.

Aim 1

Data will be extracted from two EPIC data warehouses (Clarity and Cache, which are built upon an Oracle Server relational database) by analysts who are employed by the CMC Hospital data center, and data will be sent in an encrypted Microsoft Excel file by a secure link to Data. Data will be stored in a de-identified Excel database that will be maintained by the study biostatistician. Data will be stored in a password-protected folder on a hard drive that is backed up nightly and that is accessible only to the PI and authorized study personnel. Any printouts of data will be maintained in a locked, secured file cabinet accessible only to
authorized study personnel and located in the biostatistician’s locked office. All hardcopies will be shredded at the conclusion of the study.

**Aim 2**

Pediatrician surveys will include information on gender, race/ethnicity, languages spoken, and self-efficacy in discussing preventative-health topics. Child BMI will be determined using the average of two measurements of weight and height (collected according to each clinic’s standardized protocol) at the *index* and follow-up *well-child visit one year later*. Any interim measurements of heights and weights will be recorded (see Appendix 2). To examine pediatrician-patient communication content, well-child visits will be video-recorded with a small, *wall-mounted* video camera placed unobtrusively in the exam room. Following the visit, the patient/parent will complete surveys assessing child age, gender, race/ethnicity, *parental weights, heights, educational level*, the primary language spoken at home, English proficiency, family income, health status, pediatrician participatory-decision-making style, and whether the pediatrician discussed weight during the visit. Health behaviors in the child will be assessed at each well-child visit. During the one-year interval between well-child visits, patients’ healthcare visits, labs, medications, and referrals will be tracked through the EMR at four-month intervals (Fig. 7). Pediatricians and participants will be debriefed on the specific aims of the study after the one-year follow-up visit (for patient-participants) or end of the study (pediatricians) (Fig. 7).

**Aim 3**

Pediatrician and patient surveys will include the information collected in Aim 2. Unlike in the **Aim 2** study, in **Aim 3**, both pediatricians and participants will be informed of the specific aims of the study. Pediatricians will be randomized to the intervention or standard practice. To determine whether pediatricians are using the effective clinical practice elements and communication content and strategies, data will be collected on pediatrician-patient communication at baseline (with one patient) and after intervention pediatricians receive training, and control pediatricians receive printed copies of the AAP recommendations regarding the assessment and treatment of childhood overweight and obesity.¹⁶

After pediatricians in clinics randomized to the intervention are video-recorded in a patient encounter, they will receive training on communication skills and clinical practice elements that promote successful weight management among OW school-age children. Then, following completion of the training, to determine whether pediatricians in intervention clinics are using the effective communication strategies, we will video record pediatrician-patient communication during a well-child visit. The primary outcome, use of the communication strategies and clinical practice elements, will be determined by reviewing the video-recorded primary-care visits, with coding of the communication content for patient-centeredness and specific assessment, counseling, and reassessment content. For the secondary outcomes, pediatricians’ self-reported competence will be assessed using a five-point Likert scale, and patient/parent’s self-reported pediatrician participatory-decision-making style will be elicited in the same fashion as in **Aim 2** (see Appendix 2). Feasibility and acceptability will be determined by *using acceptability and feasibility questionnaires* and conducting focused in-depth interviews of pediatricians and patient-participants, using semi-structured, open-ended questions.

Measures to ensure strict confidentiality of research data will include: 1) deletion of all personal identifiers on data collection forms after the studies have been terminated; 2) restriction of access to data to the research team only; 3) training of research staff on methods of maintaining strict confidentiality; 4) electronic data storage on password-protected computers; 5) storage of any hard copies of data in locked file cabinets accessible only by the research team; and 6) shredding of any documents containing study data and deletion of all video files of well-child visits after RIAS coding and transcription (of specific content areas). For the **Aims 2 and 3** studies, a Certificate of Confidentiality also will be obtained from the Department of Health and Human Services to protect the confidentiality of potentially sensitive information revealed by participants regarding health information. For the **Aim 3** study, a data-safety monitoring board will be convened.

**3. Potential Risks**

No potential adverse events are anticipated for patients or pediatricians because they will not see or hear the video-recorded encounters. The main risks of this study include discomfort related to having the well-child visit video-recorded, and loss of confidentiality. If confidentiality is breached, information regarding how pediatricians communicate with patients may result in embarrassment. For the patients, if confidentiality is breached, loss of sensitive health information also could lead to embarrassment and psychological discomfort.
To minimize these risks, participants will be provided with a study introduction and overview that will explain the study timeline and procedures, and list contact information for study personnel should they have any questions, concerns, or wish to withdraw from the study. They also will be given a copy of the signed written informed consent and HIPAA documents. Prior to starting the video-recorder, the pediatrician and participants will be informed that they may request to stop the recorder at any time, should they become uncomfortable. It will be made clear to participants that their participation is completely voluntary. Participants will be told that their medical care will not be affected if they choose not to participate in the study. To reduce any discomfort, inconvenience, or burden, and as a compensation for time and effort, honoraria will be provided to all participants. At the end of the Aim 2 study, pediatricians and patient-participants will be debriefed regarding the specific aims of the study. Additional measures to minimize these risks through procedures to maintain confidentiality are described below (listed in Protections Against Risk).

B. Adequacy of Protection Against Risks

1. Recruitment and Informed Consent

The PI's primary mentor, Dr. Flores, has extensive experience in optimizing participant recruitment and retention in large-scale clinic- and community-based studies, including randomized trials and audiotaped communication studies, and the PI has successfully recruited a similar group of parents of school-age children in a study consisting of focus groups. Strategies that have proved successful in enhancing recruitment and retention, and that have been incorporated into the study design of the proposed projects include: 1) collaboration with clinics for which the PI and Dr. Flores have existing relationships; 2) providing participant honoraria; and 3) using multiple approaches to ensure optimal participant recruitment and retention, including routinely collecting multiple phone numbers (home, cell, work, and parents) and other contact information (addresses for e-mail, home, work, and those of relatives and friends) for each participant, and having research staff make follow-up and reminder phone calls to participants and their parents.

Aim 1

De-identified EMR records will be used for participants (cases and controls).

Aims 2 and 3

Written informed consent for pediatricians and one consenting parent, and written patient assent (when the child is of the appropriate age) will be obtained at the pediatric practices by either the PI or her research assistant (Fig. 7). Pediatricians will be e-mailed an invitation to participate, and visited at their clinic to provide further explanation of the study and obtain written informed consent. Potential participants will be identified by reviewing pediatricians' scheduled patient records (under a HIPAA waiver). Participants will be recruited sequentially prior to the well-child visit. The research assistant will inform the patient/parent about the study and obtain informed parental consent and child assent (when appropriate). The research assistant will translate into Spanish all study documents and informed consents, consent all LEP participants, and assist them with survey completion (surveys will be administered orally by the research assistant for patients and families to avoid any issues with low literacy).

During the consent/assent process, eligible participants will be informed that the study will consist of video-recording well-child visits with the child's pediatrician to examine the content and quality of pediatrician-patient communication, that their medical care will not be adversely affected if they decline participation, and that they can discontinue participation at any time during the study.

At no point will potential enrollees be pressured or coerced to participate in this study. All participants will receive detailed explanation of the study procedures, as well as the potential risks, benefits, and alternatives. They will be provided a copy of the document for their records, and the original copy will be kept in their permanent files.

Pediatricians and participants will be debriefed on the specific aims of the Aim 2 study after the one-year follow-up visit (for patient-participants) or end of the study (pediatricians) (Fig. 7).

2. Protections Against Risk

Research subjects have the right to privacy. Any information that is collected for this research will remain confidential, as required by law. The potential risks are loss of confidentiality. If confidentiality is breached, information which participants have revealed in the well-child visit or survey may result in embarrassment.
These risks will be minimized through procedures to ensure strict confidentiality, including: 1) deletion of all personal identifiers on data collection forms after the studies have concluded; 2) restriction of access to data to the research team only; 3) training of research staff on methods of maintaining strict confidentiality; 4) electronic data storage on password-protected computers; 5) storage of any hard copies of data in locked file cabinets accessible only by the research team; and 6) shredding of any documents containing study data and deletion of all video files after RIAS coding and transcription (of specific content areas). As described above, pediatricians and participants may refuse or withdraw their consent/assent to participate, or opt to allow audio-taping only at any time. For the survey, participants may refuse to answer any question that causes discomfort.

To protect the confidentiality of well-child visit discussions, a Certificate of Confidentiality will be obtained from the NIH so that we cannot be forced to disclose information that may identify participants, even by court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. Participants will be informed of the Certificate of Confidentiality, and the protections provided by the Certificate will be explained to participants.

The study's specific aims will be revealed to the pediatricians and patient participants in a debriefing at the end of the study.

C. Potential Benefits of the Proposed Research to Human Subjects and Others

In the Aims 1 and 2 studies, there will be no direct medical benefit to the participants.

The information obtained through the studies, however, will lead to the design and implementation of primary care weight-management interventions for overweight, school-age children. Pediatrician and patient/parent participants may directly benefit from the pilot intervention: Pediatricians may improve their self-reported competency in communicating and using specific effective clinical practice elements when addressing weight and weight management, and patients may improve their weight status as a result of pediatricians' use of the effective practice elements and communication strategies. Benefits to society include providing a data-driven evidence base for effective weight-management assessment, treatment, and communication strategies in primary care for overweight children that can be integrated into successful primary care weight-management interventions, and information about how to activate children's and parents' intrinsic motivation to manage the child's weight.

D. Data and Safety Monitoring Plan

Participants' and pediatricians' safety will be monitored by maintaining ongoing contact between the research assistant, the PI, the PI's mentors and advisors, and medical directors at the participating practices. Mechanisms for reporting adverse events to the study PI and IRB will include: 1) the research assistant and all study personnel will be trained and provided with a written protocol that instructs them to contact the PI if an adverse event occurs; 2) the PI (or research assistant, particularly for LEP participants) will follow-up with participants within 48 hours to ensure that the event has been resolved and to document actions taken; and 3) all non-medical adverse events will be reported to the PI at regular monthly meetings and to the IRB via annual progress reports.

All research projects conducted at UT Southwestern are required to have yearly IRB review. Reports of adverse events are required as part of these progress reports. The PI will be responsible for contacting the Project Officer in the event that any action occurs. To assure data accuracy and reduce the chance for data error entry, all Aim 1 data will be uploaded into data-protected SAS files. Survey data from paper-and-pencil surveys will be double entered by the research assistant and checked biweekly by the study PI. Observational data will be digitally recorded, and the password-protected video-files will be sent via certified mail to the project manager at the consortium site (Susan Larson at Johns Hopkins). The files will be coded by professional coders using a standardized protocol. Prior to and after coding, digital files will be stored in a password-protected computer file to which only the project manager (Susan Larson) at Johns Hopkins will have access. Ms. Larson will supervise the coding and data management at Johns Hopkins throughout the project (in Years 1 and 2). She has over 20 years of experience in training and supervising coders and administering research projects. She will log, distribute, and track recordings, in addition to performing random periodic checks on performance, and establishing a statistical database using the RIAS data. The de-identified, password-protected database will be sent to the PI via a secure password-protected electronic file.
A detailed Data Safety and Monitoring Plan will be submitted to the UT Southwestern and Children's Medical Center IRBs prior to study recruitment. Because the Aim 3 study is a multi-site randomized controlled trial, a data-safety monitoring board will be convened.

E. ClinicalTrials.gov Requirements

The Aim 3 cluster randomized trial will be registered in ClinicalTrials.gov.
15. INCLUSION OF WOMEN AND MINORITIES

1. The proposed research will have equal gender inclusion, the target population includes two clinics that primarily serve racial/ethnic minority children, and the study does not exclude participation of limited-English-proficient (LEP) patients. The research also will include pediatricians who will have equal gender inclusion. We will include pediatricians who are racial/ethnic minorities and bilingual/fluent in Spanish. Please see the Targeted/Planned Enrollment section for detailed information regarding the numbers of women and minorities that will be included in this research.

2. The target population for the studies is overweight school-age children of both genders and diverse racial and ethnic groups, presenting for well-child visits. The target population of pediatricians is primary-care providers that follow school-age children.

3. No racial/ethnic group will be excluded from study participation.

4. The study, by design, will aim to enroll a representative population of minority children by including a federally-qualified health center and a hospital-based clinic that primarily care for minority children, and by including LEP children. Inclusion of private-practice clinics allows recruitment of Asian and non-Latino white children, because of limited enrollment of these groups from CMC-based clinics. There will be no preference or bias regarding the gender of participants in the proposed research studies.
The proposed research will have equal gender inclusion. The target population for the Aim 1 study is 6-12 year-old overweight (BMI ≥85th%) children. The target populations for the Aims 2 and 3 studies include primary-care pediatricians, overweight, 6-12 year-old school-age children, and the child's primary-caretaker (parent/guardian). Participants will be recruited to reflect the proportions of racial/ethnic minorities seen at the recruitment practices. In the targeted/planned enrollment table that follows, the currently increasingly accepted convention is followed of providing mutually exclusive racial/ethnic categories (rather than arbitrarily assigning race to Latinos/Hispanics):

**Study Title:** Aim 1 (6-12 year-old children with a BMI ≥85th%)

**Total Planned Enrollment:** 4,000

### AIM 1 Targeted/planned enrollment table: Number of subjects anticipated by ethnicity and race

<table>
<thead>
<tr>
<th>Racial/Ethnic Categories</th>
<th>Females</th>
<th>Males</th>
<th>Unknown or Not Reported</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hispanic or Latino</td>
<td>1,200</td>
<td>1,200</td>
<td>0</td>
<td>2,400</td>
</tr>
<tr>
<td>Black or African-American</td>
<td>600</td>
<td>600</td>
<td>0</td>
<td>1,200</td>
</tr>
<tr>
<td>American Indian/Alaska Native</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Asian</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Native Hawaiian or Other Pacific Islander</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>White</td>
<td>200</td>
<td>200</td>
<td>0</td>
<td>400</td>
</tr>
<tr>
<td>More Than One Race</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Unknown or Not Reported</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td><strong>Racial/Ethnic Categories: Total of All Subjects</strong></td>
<td><strong>2,000</strong></td>
<td><strong>2,000</strong></td>
<td><strong>0</strong></td>
<td><strong>4,000</strong></td>
</tr>
</tbody>
</table>
Study Title: Aim 2 (primary-care pediatricians)
Total Planned Enrollment: 15 pediatricians will be video recorded

<table>
<thead>
<tr>
<th>Racial/Ethnic Categories</th>
<th>Females</th>
<th>Males</th>
<th>Unknown or Not Reported</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hispanic or Latino</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Black or African-American</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>American Indian/Alaska Native</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Asian</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Native Hawaiian or Other Pacific Islander</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>White</td>
<td>5</td>
<td>5</td>
<td>0</td>
<td>10</td>
</tr>
<tr>
<td>More Than One Race</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Unknown or Not Reported</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Racial/Ethnic Categories: Total of All Subjects</td>
<td>8</td>
<td>7</td>
<td>0</td>
<td>15</td>
</tr>
</tbody>
</table>

Study Title: Aim 2 (six- to 12-year-old children with a BMI ≥85th%)  
Total Planned Enrollment: 85

<table>
<thead>
<tr>
<th>Racial/Ethnic Categories</th>
<th>Females</th>
<th>Males</th>
<th>Unknown or Not Reported</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hispanic or Latino</td>
<td>21</td>
<td>21</td>
<td>0</td>
<td>42</td>
</tr>
<tr>
<td>Black or African-American</td>
<td>6</td>
<td>6</td>
<td>0</td>
<td>12</td>
</tr>
<tr>
<td>American Indian/Alaska Native</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Asian</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Native Hawaiian or Other Pacific Islander</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>White</td>
<td>12</td>
<td>12</td>
<td>0</td>
<td>24</td>
</tr>
<tr>
<td>More Than One Race</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Unknown or Not Reported</td>
<td>4</td>
<td>3</td>
<td>0</td>
<td>7</td>
</tr>
<tr>
<td>Racial/Ethnic Categories: Total of All Subjects</td>
<td>43</td>
<td>42</td>
<td>0</td>
<td>85</td>
</tr>
</tbody>
</table>
Study Title: Aim 2 (parents of 6-12 year-old children with a BMI ≥85th %)
Total Planned Enrollment: 85

**AIM 2 Targeted/planned enrollment table:** Number of parents anticipated by ethnicity and race

<table>
<thead>
<tr>
<th>Racial/Ethnic Categories</th>
<th>Females</th>
<th>Males</th>
<th>Unknown or Not Reported</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hispanic or Latino</td>
<td>21</td>
<td>21</td>
<td>0</td>
<td>42</td>
</tr>
<tr>
<td>Black or African-American</td>
<td>6</td>
<td>6</td>
<td>0</td>
<td>12</td>
</tr>
<tr>
<td>American Indian/Alaska Native</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Asian</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Native Hawaiian or Other Pacific Islander</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>White</td>
<td>14</td>
<td>14</td>
<td>0</td>
<td>28</td>
</tr>
<tr>
<td>More Than One Race</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Unknown or Not Reported</td>
<td>2</td>
<td>1</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td><strong>Racial/Ethnic Categories: Total of All Subjects</strong></td>
<td><strong>43</strong></td>
<td><strong>42</strong></td>
<td><strong>0</strong></td>
<td><strong>85</strong></td>
</tr>
</tbody>
</table>
**Study Title:** Aim 3 (pediatricians)
**Total Planned Enrollment:** 30 (the targeted proportions of pediatricians for each of the racial/ethnic groups will depend, in part, on the proportions of minority pediatricians within the practices recruited)

**AIM 3 Targeted/planned enrollment table:** Number of pediatricians anticipated by ethnicity and race

<table>
<thead>
<tr>
<th>Racial/Ethnic Categories</th>
<th>Females</th>
<th>Males</th>
<th>Unknown or Not Reported</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hispanic or Latino</td>
<td>4</td>
<td>4</td>
<td>0</td>
<td>8</td>
</tr>
<tr>
<td>Black or African-American</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>American Indian/Alaska Native</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Asian</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Native Hawaiian or Other Pacific Islander</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>White</td>
<td>5</td>
<td>5</td>
<td>0</td>
<td>10</td>
</tr>
<tr>
<td>More Than One Race</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Unknown or Not Reported</td>
<td>4</td>
<td>4</td>
<td>0</td>
<td>8</td>
</tr>
<tr>
<td><strong>Racial/Ethnic Categories: Total of All Subjects</strong></td>
<td><strong>15</strong></td>
<td><strong>15</strong></td>
<td><strong>0</strong></td>
<td><strong>30</strong></td>
</tr>
</tbody>
</table>

**Study Title:** Aim 3 (6-12 year-old children with a BMI ≥85th %)
**Total Planned Enrollment:** 60

**AIM 3 Targeted/planned enrollment table:** Number of children anticipated by ethnicity and race

<table>
<thead>
<tr>
<th>Racial/Ethnic Categories</th>
<th>Females</th>
<th>Males</th>
<th>Unknown or Not Reported</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hispanic or Latino</td>
<td>15</td>
<td>15</td>
<td>0</td>
<td>30</td>
</tr>
<tr>
<td>Black or African-American</td>
<td>5</td>
<td>5</td>
<td>0</td>
<td>10</td>
</tr>
<tr>
<td>American Indian/Alaska Native</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Asian</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Native Hawaiian or Other Pacific Islander</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>White</td>
<td>10</td>
<td>10</td>
<td>0</td>
<td>20</td>
</tr>
<tr>
<td>More Than One Race</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Unknown or Not Reported</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td><strong>Racial/Ethnic Categories: Total of All Subjects</strong></td>
<td><strong>30</strong></td>
<td><strong>30</strong></td>
<td><strong>0</strong></td>
<td><strong>60</strong></td>
</tr>
</tbody>
</table>
**Study Title:** Aim 3 (parents of 6-12 year-old children with a BMI ≥85th %)

**Total Planned Enrollment:** 60

**AIM 3 Targeted/planned enrollment table:** Number of parents anticipated by ethnicity and race

<table>
<thead>
<tr>
<th>Racial/Ethnic Categories</th>
<th>Females</th>
<th>Males</th>
<th>Unknown or Not Reported</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hispanic or Latino</td>
<td>15</td>
<td>15</td>
<td>0</td>
<td>30</td>
</tr>
<tr>
<td>Black or African-American</td>
<td>5</td>
<td>5</td>
<td>0</td>
<td>10</td>
</tr>
<tr>
<td>American Indian/Alaska Native</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Asian</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Native Hawaiian or Other Pacific Islander</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>White</td>
<td>10</td>
<td>10</td>
<td>0</td>
<td>20</td>
</tr>
<tr>
<td>More Than One Race</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Unknown or Not Reported</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td><strong>Racial/Ethnic Categories: Total of All Subjects</strong></td>
<td>30</td>
<td>30</td>
<td>0</td>
<td>60</td>
</tr>
</tbody>
</table>
17. INCLUSION OF CHILDREN

Children who are 6-12 years old and overweight (BMI ≥85th percentile) are the sole focus of the proposed research, as the studies are aimed at identifying how pediatricians can help these children improve their relative weight in primary care. The PI is a pediatrician who has conducted prior studies of children in this age group. The PI’s primary mentor, Dr. Flores, is a pediatrician and pediatric health services researcher with extensive experience and expertise working with children of all ages, and has previously conducted studies with 6-12 year-old children. Dr. Roter has over 30 years of experience conducting communication studies, including with school-age children, exploring the triadic relationship between pediatricians, children, and parents. Dr. Barlow is a pediatrician with expertise working with children in the clinical and research setting. Dr. Wiebe has conducted multiple studies on adherence research, and has extensive experience validating survey instruments in children. The studies will be conducted in three primary-care clinics in the Dallas area, where pediatricians and staff also have considerable experience working with children, and the facilities are specifically designed for the evaluation and treatment of children.
Consortium/Johns Hopkins

Transcription and interaction analysis costs are budgeted in Year 1 at $\text{[Redacted]}$, and in Year 2 at $\text{[Redacted]}$. Note: The consortium site does not start on the same date as the primary site. It will start on 1/1/2014.

The rationale for outsourcing the coding of the recorded visits is that the reliability of the RIAS measures, and particularly the measure of patient-centeredness, is proportional to the amount of time and training of the coders. Additionally, Johns Hopkins has professional coders who are bilingual in English and Spanish, and can code visits performed in both languages. Coding of 85 digital files of pediatric well-child visits will be performed. This number includes a random sample of 10 files drawn throughout the coding period for double coding to establish inter-coder reliability. Calculation and report of coder reliability will be performed and a SPSS data file of the RIAS coding will be prepared.

Debra Roter (no salary requested) will act as a mentor on communication issues for \text{[Redacted]}, assisting her with study design, instrumentation, statistical analysis of study data, and manuscript preparation.

Susan Larson (no salary requested) will have primary responsibility for the overall scientific integrity of the project in regard to videotape analysis, including performance of the coders. She will act as the research and administrative assistant responsible for coder monitoring and supervision and data management throughout the project. Ms. Larson has over 20 years of experience in training and supervising coders in using the RIAS and administering research projects. Data management will include logging, distributing, and tracking recordings to coders, holding weekly coders meetings, monitoring coders’ performance for accuracy, and establishing reliability by periodic random reliability checks on performance and the establishment of a statistical database using the RIAS data. This includes special expertise in extracting the data set from the RIAS software, but eliminates the need for separate data entry.

Coding costs: We have budgeted for a total of 30% coder time for 85 recordings, allocating approximately six coding hours per encounter.
Primary Investigator/Program Director (Last, first, middle):

PHS is awarded to the statements or claims may subject me to the statements or claims may subject me to

E-Mail: dsparks@jhsph.edu E-Mail: dsparks@jhsph.edu

Tel: 410 966 6498 FAX: 410 955 7241

E-MAIL ADDRESS: dsparks@jhsph.edu

Response to Specific Request for Applications or Program Announcement or Solicitation

Number: PA-11-194 Title: Mentored Patient-Oriented Research Career Development Award Parent (K23)

Program Director/Principal Investigator

NAME (Last, first, middle) 3a. Roter, Debra

DEGREE(S) 3b. Dr. PH

era Commons User Name 3c. drorder1

MAILING ADDRESS (Street, city, state, zip code) 3d. 624 N. Broadway

Hampton House 750A

Baltimore, MD 21205

HUMAN SUBJECTS RESEARCH

1a. Research Exempt

2a. No ☒ Yes ☐

4b. Federal-Wide Assurance No. 3d. NIH-defined Phase III Clinical Trial

FWA00000287 ☐ No ☒ Yes

VERTEBRATE ANIMALS

5a. Animal Welfare Assurance No. A3272-01

☐ No ☒ Yes

DATES OF PROPOSED PERIOD OF SUPPORT (month, day, year—MM/DD/YYYY)

6a. From 06/01/2014 Through 05/31/2015

7. COSTS REQUESTED FOR INITIAL BUDGET PERIOD

7e. Direct Costs ($) ☐ 11. ENTITY IDENTIFICATION NUMBER

7f. Total Costs ($) ☐ 1520565110-A5

8. COSTS REQUESTED FOR PROPOSED PERIOD OF SUPPORT

10. TYPE OF ORGANIZATION

10a. Direct Costs ($) ☐ 11b. DUNS NO. 00-191-0777

10b. Total Costs ($) ☐ Corp. District MD-7th

APPLICANT ORGANIZATION

Name: Johns Hopkins University

Address: 615 N. Wolfe Street

Office of Research Administration

W1600

Baltimore, MD 21205

ADMINISTRATIVE OFFICIAL TO BE NOTIFIED IF AWARD IS MADE

Name: Denise Sparks

Title: Sr. Grants Associate

Address: 615 N. Wolfe Street

W1600

Baltimore, MD 21205

Tel: 410 614 1856 FAX: 410 955 0258

E-Mail: dsparks@jhsph.edu

APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

SIGNATURE OF OFFICIAL NAMED IN 13. (In ink. “Ph” signature not acceptable.)

DATE 3/4/13

OMB No. 0925-0001

Page 111
STATEMENT OF INTENT TO ESTABLISH
A COLLABORATION

Date: 03/01/2013

Proposal Title: Primary Care, Communication, and Improving Overweight Children's Weight Status

Proposed Project Period: 06/01/2014 - 05/31/2015

Total Proposed Amount: [Redacted]

JHSPH Principal Investigator: Dr. Debra Roter

The appropriate programmatic and administrative personnel of Johns Hopkins Bloomberg School of Public Health ("JHSPH") involved in this grant application are aware of the NIH grant policy and are prepared to establish the necessary inter-institutional agreement consistent with that policy.

In addition, JHSPH certifies that it has a Policy on Financial Conflicts of Interest in Research in place which complies with 42 C.F.R. Part 50 and will follow such policy with regards to this proposal. If an award is received, JHSPH will continue to follow such policy throughout the life of the award. JHSPH also certifies that the Principal investigator listed above and all Investigators listed below have no conflicts to disclose, or have completed a disclosure in accordance with their Conflict of Interest policy.

JHSPH's Investigators on this project are listed below:

____ Susan Larson

____

____

____

Johns Hopkins Bloomberg School of Public Health
Collaborating Institution

[Signature]

Date: 03/01/2013

Collaborator Principal Investigator

[Signature]

Date: 04/13

Official Authorized to Sign for the Collaborating Institution

[Signature]

Date:

Protecting Health, Saving Lives—Millions at a Time

615 North Wolfe Street • Baltimore, Maryland 21205 • www.jhsph.edu
PROJECT SUMMARY (See instructions):
Primary activities are twofold: (1) mentoring and advising the PI on study design, analysis and manuscript preparation in regard to recorded pediatric weight management visits, and, (2) RIAS coding of 85 of these visits (including a random sample of 10 visits drawn throughout the coding period for double coding to establish inter-coder reliability) and preparation of an SPSS data file for use in analysis.

RELEVANCE (See instructions):

PROJECT/PERFORMANCE SITE(S) (if additional space is needed, use Project/Performance Site Format Page)

<table>
<thead>
<tr>
<th>Project/Performance Site Primary Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>Organizational Name: Johns Hopkins University</td>
</tr>
<tr>
<td>DUNS: 00-191-0777</td>
</tr>
<tr>
<td>Street 1: 624 N. Broadway</td>
</tr>
<tr>
<td>Street 2: HH 750A</td>
</tr>
<tr>
<td>City: Baltimore</td>
</tr>
<tr>
<td>County:</td>
</tr>
<tr>
<td>State: MD</td>
</tr>
<tr>
<td>Province:</td>
</tr>
<tr>
<td>Country: USA</td>
</tr>
<tr>
<td>Zip/Postal Code: 21205</td>
</tr>
<tr>
<td>Congressional Districts: MD-7th</td>
</tr>
</tbody>
</table>

Additional Project/Performance Site Location

| Organizational Name: |
| DUNS: |
| Street 1: |
| Street 2: |
| City: |
| County: |
| State: |
| Province: |
| Country: |
| Zip/Postal Code: |
### SCIENTIFIC KEY PERSONNEL

See instructions. Use continuation pages as needed to provide the required information in the format shown below. Start with Program Director(s)/Principal Investigator(s). List all other key personnel in alphabetical order, last name first.

<table>
<thead>
<tr>
<th>Name</th>
<th>eRA Commons User Name</th>
<th>Organization</th>
<th>Role on Project</th>
</tr>
</thead>
<tbody>
<tr>
<td>Debra Roter</td>
<td>droter1</td>
<td>JHU</td>
<td>Site PI</td>
</tr>
<tr>
<td>Susan Larson</td>
<td>slarson</td>
<td>JHU</td>
<td>Site Co-Inv.</td>
</tr>
</tbody>
</table>

### OTHER SIGNIFICANT CONTRIBUTORS

<table>
<thead>
<tr>
<th>Name</th>
<th>Organization</th>
<th>Role on Project</th>
</tr>
</thead>
</table>

### Human Embryonic Stem Cells

- **Yes**

If the proposed project involves human embryonic stem cells, list below the registration number of the specific cell line(s) from the following list:


If a specific line cannot be referenced at this time, include a statement that one from the Registry will be used.

| Cell Line |
SUMMARY STATEMENT

Application Number: 1 K23 HL118152-01A1

PROGRAM CONTACT:
Josephine Boyington
301-594-2542
boyingtonje@mail.nih.gov

Principal Investigator

Applicant Organization: UT SOUTHWESTERN MEDICAL CENTER

Review Group: ZHL1 CSR-X (O1)
National Heart, Lung, and Blood Institute Special Emphasis Panel
K23, K24, K25 Research Career Development Awards

Meeting Date: 06/13/2013
Council: OCT 2013
Requested Start: 09/01/2013

Project Title: Primary Care, Communication, & Improving Children’s Health
SRG Action: Impact Score: 14

Human Subjects: 30-Human subjects involved - Certified, no SRG concerns
Animal Subjects: 10-No live vertebrate animals involved for competing appl.
Gender: 1A-Both genders, scientifically acceptable
Minority: 1A-Minorities and non-minorities, scientifically acceptable
Children: 1A-Both Children and Adults, scientifically acceptable
Clinical Research - not NIH-defined Phase III Trial

<table>
<thead>
<tr>
<th>Year</th>
<th>Direct Costs Requested</th>
<th>Estimated Total Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>137,431</td>
<td>148,425</td>
</tr>
<tr>
<td>2</td>
<td>139,320</td>
<td>150,466</td>
</tr>
<tr>
<td>3</td>
<td>128,065</td>
<td>138,310</td>
</tr>
<tr>
<td>4</td>
<td>130,449</td>
<td>140,886</td>
</tr>
<tr>
<td>5</td>
<td>128,465</td>
<td>138,742</td>
</tr>
<tr>
<td>TOTAL</td>
<td>663,730</td>
<td>716,828</td>
</tr>
</tbody>
</table>

ADMINISTRATIVE BUDGET NOTE: The budget shown is the requested budget and has not been adjusted to reflect any recommendations made by reviewers. If an award is planned, the costs will be calculated by Institute grants management staff based on the recommendations outlined below in the COMMITTEE BUDGET RECOMMENDATIONS section.
1K23HL118152-01A1

Notice: All Career Development (K) applications received after January 25, 2010 will be required to use the restructured applications forms and conform to the new page limits. See NOT-OD-10-002 for further clarification http://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-027.html and Table of Page Limits from the Office of Extramural Research, NIH http://grants.nih.gov/grants/forms_page_limits.htm for additional guidance. An application not adhering to these page limits may be administratively withdrawn, please see http://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-080.html.

NHLBI “K” series resubmission/amended application due date is Mar. 12, July 12, or Nov. 12. In addition, a Letter of Intent (LOI) is requested from applicants who are planning to submit a resubmission application. The LOI should be submitted by February 12, June 12, or October 12 (one month in advance of the submission date). Submit LOI to nhlbichefreviewbranch@nhlbi.nih.gov

Note: NIH will accept only a single amendment to the original application: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-003.html

Please be advised that NIH has adopted a new policy for accepting Post-Submission Application Materials. Please see the following link and related notices for a description of acceptable and unacceptable post-submission application materials: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-091.html

CRITIQUES

The comments in the CRITIQUE section were prepared by the reviewers assigned to this application and are provided without significant modification or editing by staff. They are included to indicate the range of comments made during the discussion and may not reflect the final outcome. The RESUME AND SUMMARY OF DISCUSSION section summarizes the final opinion of the committee after discussion and is the basis for the assigned priority score.

RESUME AND SUMMARY OF DISCUSSION: This is a resubmission of a K23 application from Dr. in which she will address physician/patient interaction and communication to improve the weight management of children. The Candidate remains very strong, although concerns persist about her career progression as the previous criticism about her appointment of Instructor; this has not been addressed to the satisfaction of some of the reviewers. However, the reviewers agreed that the Candidate has been very responsive to their previous concerns, and the current version is considerably improved. The Career Development Plan is very strong. The Research Plan is innovative, and the specific aims well-written. There were some minor weaknesses in the RP that were discussed; the proposed research will not identify the causal pathways/relationships for aims 1 and 2; the proposed research assumes that current practices by pediatricians to promote weight management are working - this should be addressed; and, the sample size calculations for aim 2 are inadequate. The application was rated in the Outstanding to Exceptional range - extremely strong with negligible to no weaknesses.

DESCRIPTION (provided by applicant): Childhood overweight is an important public-health problem in the US. Current estimates indicate that one in three children is overweight. Over half of overweight 5-10 year-old children have at least one cardiovascular disease risk factor, and overweight increases the lifetime risk of cardiovascular morbidity and premature death, but these risks are reduced in overweight children who attain a normal weight. During well-child visits, pediatricians have an opportunity to address weight and weight-management. Little is known, however, about clinical practice elements and pediatrician-patient communication strategies associated with weight improvement in overweight children. The overall objective of the proposed project is to identify specific clinical practice elements and pediatrician-patient communication strategies during well-child visits that predict improvement in relative weight among overweight children. This will be accomplished through three specific aims, which are to 1) identify specific clinical practice elements in pediatric primary care that predict
improvement in weight status; 2) determine communication strategies that predict improvement in weight status; and 3) develop and test the feasibility and acceptability of a pilot intervention to improve pediatricians' communication and use of specific clinical practice elements when addressing weight and weight management during primary-care visits with overweight children. For Aim 1, electronic medical records (EMR) will be analyzed to determine clinical practice elements (such as lab assessments and follow-up interval) associated with improvement in weight status at one year follow-up. For Aim 2, Roter Interaction Analysis of video-recorded well-child visits will be used to analyze pediatrician-patient communication regarding weight and weight-management (including assessment and counseling regarding overweight status, and communication dynamics, including patient-centeredness), and children will be followed, by tracking interval visits, weights/heights, and referrals using the EMR, over one year. Findings from Aims 1 and 2 will be used in Aim 3 to develop and test the feasibility and acceptability of a pilot intervention aimed at improving pediatricians' observed and self-reported competence in using specific clinical practice elements and effective communication when addressing overweight during primary-care visits, compared with a control group of standard practice. The proposed Career Development Award addresses how to improve overweight/obesity management in primary care, a research priority of an NHLBI Working Group convened to set future research priorities in childhood obesity prevention and treatment. The exceptional resources and institutional support at UT Southwestern, outstanding multi-disciplinary mentorship team, and proposed career development activities will allow the candidate to achieve her long-term goal of becoming an independent investigator and nationally recognized expert on primary-care based interventions that are effective in improving childhood overweight and obesity.

PUBLIC HEALTH RELEVANCE: There is an urgent need to identify strategies that lead to successful weight improvement for overweight children: although overweight increases the lifetime risk of heart disease and early death, these risks are reduced in overweight children who attain a healthy weight by adulthood. The goal of the proposed research is to identify specific clinical practice elements and communication strategies in pediatric primary care that pediatricians already are using which help children attain healthier relative weights, and pilot an intervention to translate study findings into clinical practice. Achievement of the study aims has the potential to be a significant contribution to promoting weight improvement for overweight children, as the proposed research could lead to the development of an effective intervention to improve pediatricians' communication and use of specific clinical practice elements when addressing weight and weight management for overweight children in primary care.

CRITIQUE 1:

Candidate: 2
Career Development Plan/Career Goals /Plan to Provide Mentoring: 2
Research Plan: 2
Mentor(s), Co-Mentor(s), Consultant(s), Collaborator(s): 1
Environment and Institutional Commitment to the Candidate: 3

Overall Impact:
This is an excellent candidate who is already becoming a national leader in the field. Her publication track record is good and significantly improved from her prior submission. The primary mentor and mentoring team are outstanding. The research plan is innovative and important and has a few negligible limitations as noted below. The institutional commitment is generally strong, although the candidate's position as an instructor is not addressed despite critiques about this in the last review. Other than this latter issue, this revised application is very responsive to the prior reviews.

1. Candidate:
Strengths
• [Redacted] received her MD at Johns Hopkins and did a Med-Peds residency at Duke where she also completed a Health Services Research Fellowship and received an MHS in clinical research in May of 2010.
• The candidate has four first-authored research publications in the peer review literature and each are in the field of this K23 application. Three of these publications have been added since the prior submission which represents a very responsive revised application since the publication record was one of the criticisms in the prior submission.
• The candidate has conducted significant research in the area of weight management for children and has gained a national reputation for this work as evidenced by being selected as the Chair-elect of the Obesity Society Clinical Management Section.

Weaknesses
• The candidate has been an Instructor in Internal Medicine and Pediatrics at UTSW since January 2010. This was pointed out as a potential weakness in the last review and is not adequately addressed in the revision.

2. Career Development Plan/Career Goals & Objectives/Plan to Provide Mentoring:
Strengths
• The career development plan focuses on the conduct of three specific aims: identifying clinical practice elements associated with improvement in weight status, identifying the communication methods and content associated with improvement in weight status, and developing and implementing a pilot intervention. Although the content areas of career development activities are not specifically highlighted, the courses and tasks outlined in the career development plan are appropriate to learn the skills to accomplish these aims.
• The plan for meeting with the mentors and advisors is good with frequent in person meetings for those that are local and phone contact with the mentors/advisors at a distance.

Weaknesses
• The description of the evaluation of the candidate could be more detailed to ensure that the candidate receives timely feedback that could help direct mid-course corrections.

3. Research Plan:
Strengths
• The candidate proposes to identify predictors of improvement in weight status among overweight children including 1) specific clinical practice elements in pediatric primary care (aim 1) and 2) communication content and strategy used by primary care physicians to address weight (aim 2). In addition, the candidate proposes to develop and test the feasibility of a pilot intervention that is based on aims 1 and 2. The aims are well written, innovative and important.
• The preliminary data supporting these aims is strong and relevant to the feasibility of the proposed project.

Weaknesses
• The candidate doesn't directly address the difficulty determining the causal pathways in Aims 1 and 2 and it may be that some of the clinical practices or communication approaches will predict improvement in weight status without being causal and therefore not be useful in an intervention. This concern goes beyond bias and confounding, which are addressed. However, this is the goal of the pilot and future RCT, so this is not a major limitation. Nonetheless, it would have been good to address this issue.
• This proposal assumes that pediatricians are currently doing something that is successful in addressing obesity in this population and that assumption is not adequately addressed in the application. Nonetheless, I think it is a reasonable avenue for research and not a major limitation.
• The sample size calculations for Aim 2 seem like a stretch. The proposal that only 12-46 patients are needed to detect a change in weight among these children, given the complexity of
weight change and the clustered design of this study, suggests that the proposed effect size is enormous.

- The success of Aim 3 depends on the success of Aims 1 and 2 and the timing of getting results from Aims 1 and 2 in time to inform Aim 3 will be challenging. Nonetheless, the preliminary data mitigate this concern.

4. Mentor(s), Co-Mentor(s), Consultant(s), Collaborator(s):
   **Strengths**
   - The primary mentor is Dr. Glenn Flores, who is Director of General Pediatrics and a named Chair in Pediatrics. Dr. Flores has an excellent funding track record and is currently funded by an R01 and R25 as well as a foundation grant. He has an outstanding publication track record with 168 research publications and numerous publications in the highest impact journals. His mentoring track record is also outstanding with 61 mentees that have produced 69 publications and obtained 28 grants.
   - Dr. Roter is also an outstanding co-mentor with an outstanding track record of funding and publications in the area of measuring and assessing communication. The role for Dr. Roter on this grant is specific and targeted to her expertise and her biosketch describes this nicely.
   - In addition, the team is joined by Dr. Sarah Barlow who has established a strong network of pediatric offices in the Houston area that will facilitate the proposed research and Dr. Deborah Wiebe who is a clinical health and pediatric psychologist who brings appropriate expertise in using the communication analysis approach called RIAS.

   **Weaknesses:** None

5. Environment and Institutional Commitment to the Candidate:
   **Strengths**
   - There is a strong commitment to protect 75% of the candidate's time for research and the candidate currently has 70% protected time which demonstrates current commitment to her research and research training.

   **Weaknesses**
   - The fact that the candidate has been an instructor since 2010 was mentioned as a potential weakness in the initial application and is still true and not adequately addressed in the revision.

**Protections for Human Subjects:** Acceptable Risks and Adequate Protections

Data and Safety Monitoring Plan (Applicable for Clinical Trials Only): Unacceptable
   - More detail is needed about the plans for a data and safety monitoring plan for Aim 3. This will be easy for the candidate to address, but should be addressed.

Resubmission:
   - The revised application is generally very responsive to the prior reviews, with the acceptance of addressing the candidate's promotion to Assistant Professor.

**CRITIQUE 2:**

Candidate: 1
Career Development Plan/Career Goals /Plan to Provide Mentoring: 2
Research Plan: 1
Mentor(s), Co-Mentor(s), Consultant(s), Collaborator(s): 1
Environment and Institutional Commitment to the Candidate: 1

**Overall Impact:**
This is a resubmission of an excellent initial proposal. The original proposal was reviewed in October of 2012, and resubmitted in Feb/March of 2013. This is an excellent proposal from an outstanding candidate in an ideal environment. The applicant was very responsive to the comments of the reviewers and the current proposal is markedly improved with only minimal residual concerns.

1. Candidate:
   Strengths
   - The Candidate has a long standing focused research interest in childhood obesity that started in medical school and has followed a well-planned path.
   - She has previously received a MCR from Duke.
   - She joined the faculty at UTSW in January 2010, and is an active member of their weight management program. She is well integrated into the system and has already been productive.
   - Regarding her publication record, three new first-authored publications (one in Pediatrics and two in Academic Pediatrics) and three new abstracts (one platform presentation and two posters) have been accepted since her previous submission. Overall, she has 9 original research publications, two letters, two book chapters, and 10 abstracts. She is first author on four of the original research articles.
   - The candidate is at the optimal level for support from a career development award.

   Weaknesses: None

2. Career Development Plan/Career Goals & Objectives/Plan to Provide Mentoring:
   Strengths
   - The proposed course work is aligned with specific needs to properly conduct the proposed research plan.
   - The revision has been responsive to the previous review. The applicant has outlined in more detail the oversight provided by the mentoring team.

   Weaknesses
   - The distinction of how her proposed courses add to her previous class work is still not clear. This is a very minor concern.

3. Research Plan:
   Strengths
   - The topic of childhood obesity is extremely significant, and the proposed approach is very novel. The proposed studies also build nicely in previous work from the candidate.
   - The applicant was very responsive to the concerns of the reviewers in regard to her research plan.

   Weaknesses
   - There is a lack of significant feasibility data for the second specific aim.

4. Mentor(s), Co-Mentor(s), Consultant(s), Collaborator(s):
   Strengths
   - The primary mentor, Dr. Glenn Flores, is a leader in this area of research. He has a successful track record of training junior investigators including a current trainee with a K23 award. He is well published and well funded.
   - The candidate has also assembled an excellent team of co-mentors. Their skills are complementary and well aligned with the needs of the candidate.
   - There is a plan for transitioning the applicant to independence.
   - A community pediatrician was added to the mentoring team.

   Weaknesses: None

5. Environment and Institutional Commitment to the Candidate:
Strengths

• UTSW has a strong academic research program focusing on obesity including The Taskforce on Obesity Research.
• The candidate received some research seed money, and will have 75% protected time.
• The involvements of resources from the CTSA were appropriately removed from the proposal.

Weaknesses: None

Resubmission:

• The resubmission was very responsive to the comments from the reviewers.

CRITIQUE 3:

Candidate: 1
Career Development Plan/Career Goals /Plan to Provide Mentoring: 1
Research Plan: 1
Mentor(s), Co-Mentor(s), Consultant(s), Collaborator(s): 1
Environment Commitment to the Candidate: 1

Overall Impact:
The candidate completed fellowship and Masters' level training in clinical research and has been involved in an impressive portfolio of clinical research as a junior co-investigator. She also has conducted investigator-initiated work resulting in national presentations. Since the original submission the candidate has increased her publication productivity and has conducted pilot work in areas directly related to this proposal. The candidate has established a logical trajectory of work characterized by increasing complexity in research question and methodology. The projects proposed for this K award reflect self-acquired knowledge based on hands-on experience. The candidate has been responsive to recommendations to modify the research plan. Her mentors clearly contributed to the formulation of her proposed studies, which represent a logical, well-thought out feasible plan appropriate for her level of training and experience. Thus, a particular strength of this application is that it represents the candidate's work buttressed, but not dominated, by her mentors' interests. The career plan is clearly described and comprehensive and the institutional commitment continues to be strong and enthusiastic.

1. Candidate:
Strengths

• The candidate completed a fellowship and Masters Degree in Health Services Research.
• The candidate participated in several observational and randomized trials as a co-investigator, and performed several secondary data analyses.
• The candidate conducted and analyzed her own studies and presented them at national meetings.
• The candidate has been productive since the original submission with new publications and national presentations.

Weaknesses: None.

2. Career Development Plan/Career Goals & Objectives/Plan to Provide Mentoring:
Strengths

• The proposed study includes diverse research methods and thus provides the candidate with broad experience as well as flexibility in pursuing future research studies.
• A detailed plan of coursework, conferences, and individual and group mentorship is clearly outlined.
Clear goals and timelines are presented for applications for future funding, manuscripts, and presentations. This revised application now contains a plan for transitioning to an independent investigator.

This revised application now outlines how coursework will directly enhance each study aim.

Weaknesses: None.

3. Research Plan:

Strengths

- The research aims build on each other, follow a logical sequential pattern, and are appropriate for the candidate's level of training. Modification of aim 3 to a pilot RCT makes the plan more feasible and more informative.
- Culturally diverse populations will be enrolled, thus nuances of social circumstance will be captured and will increase the generalizability of the study.
- The description of each aim is comprehensive and well thought out with attention to many methodological details.
- In this revised application information about characteristics of parents and providers and their practice priorities have been added as well as attempts to capture the nature and content of interval visits. Primary care site also has been added to the matching criteria and information about adherence to national guidelines regarding obesity preventive care will be documented.
- This research proposal with three comprehensive aims is quite ambitious, but possible given the practical experience of the candidate and the commitment of her mentors and the institution.

Weaknesses: None

4. Mentor(s), Co-Mentor(s), Consultant(s), Collaborator(s):

Strengths

- The primary mentor is an established clinical investigator with extensive NIH and Foundation support and an outstanding track record of mentoring productive junior faculty.
- Co-mentors and advisors have multidisciplinary and complementary expertise in areas that are necessary for the candidate's project. This revised application now pledges the co-mentorship of a previous advisor; reflecting a solid dedication to the candidate's career.
- Mentors and advisors provide unique non-overlapping roles and their contributions to the proposed study already are evident.
- Mentors and advisors are senior members in their institutional departments and thus they can mobilize assistance for the project as needed.

Weaknesses: None

5. Environment and Institutional Commitment to the Candidate:

Strengths

- There is strong commitment and support for concentrated time, computational and biostatistical consultation, research staff, and seed money.
- Letters from senior administrators reflect great enthusiasm for the candidate's potential to have a successful research career.
- Letters pledging collaboration are included from the Children's Medical Center Primary Care Continuity Clinic of Dallas and the Pediatric Associates of Dallas private practice. A letter of collaboration from Los Barrios Unidos Community Clinic is also now included.

Weaknesses: None

THE FOLLOWING RESUME SECTIONS WERE PREPARED BY THE SCIENTIFIC REVIEW OFFICER TO SUMMARIZE THE OUTCOME OF DISCUSSIONS OF THE REVIEW COMMITTEE ON THE FOLLOWING ISSUES:
PROTECTION OF HUMAN SUBJECTS (Resume): ACCEPTABLE; however, more detail is needed about the plans for a data and safety monitoring plan.

INCLUSION OF WOMEN PLAN (Resume): ACCEPTABLE

INCLUSION OF MINORITIES PLAN (Resume): ACCEPTABLE

INCLUSION OF CHILDREN PLAN (Resume): ACCEPTABLE; NIH definition of a child is an individual under the age of 21

TRAINING IN THE RESPONSIBLE CONDUCT OF RESEARCH: ACCEPTABLE

RESOURCE SHARING PLAN: ACCEPTABLE

COMMITTEE BUDGET RECOMMENDATIONS: The budget was recommended as requested.


The impact/priority score is calculated after discussion of an application by averaging the overall scores (1-9) given by all voting reviewers on the committee and multiplying by 10. The criterion scores are submitted prior to the meeting by the individual reviewers assigned to an application, and are not discussed specifically at the review meeting or calculated into the overall impact score. Some applications also receive a percentile ranking. For details on the review process, see http://grants.nih.gov/grants/peer_review_process.htm#scoring.