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Eunice Kennedy Shriver National Institute of
Child Health and Human Development (NICHD)

Division of Epidemiology, Statistics, *and* Prevention Research

Report to the
NACHHD Council

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EXECUTIVE SUMMARY

As an intramural division, the Division of Epidemiology, Statistics, and Prevention Research, at the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD), has an ambitious three-fold mission that includes:

- Conducting innovative high-impact research aimed at improving the health of populations;
- Training and mentoring the next cadre of public health and clinical researchers; and
- Providing professional service at varying levels.

The Division appeared on the NICHD's organizational chart five years after the Institute's founding, denoting a longstanding commitment to epidemiological, statistical, and behavioral research. The Division comprises the Office of the Director, three research Branches, a Computer Sciences Section, and the National Institutes of Health (NIH)-D.C. Initiative to Reduce Infant Mortality in Minority Populations, called the D.C. Initiative. The Division's research is conducted in its three Branches:

- The Biostatistical & Bioinformatics Branch (BBB) conducts original statistical methodologic research aimed at developing new methodologies for researchers working within the Institute's mission, while also engaging in collaborative research as a part of team science.
- The Epidemiology Branch (EB) designs and conducts reproductive, perinatal, and pediatric epidemiologic research utilizing novel study designs and methodologies.
- The Prevention Research Branch (PRB) designs and conducts research focusing on young drivers, adolescent behavior, and the family management of diabetes.

Since its last report to the National Advisory Child Health and Human Development (NACHHD) Council in 2005, the Division has successfully accomplished its mission while also expanding its scope and stature. The Division increased its research productivity not only in terms of positive publication and presentation trajectories, totaling 444 and 124 respectively, but also in terms of its research scope. In particular, the Division increased its reproductive epidemiologic research in response to the charge levied upon the Branch chief when recruited in 2000. The scope of perinatal epidemiologic research has also expanded to include both the clinical management of low-risk parturient women and etiologic research on pregnancy complications. The scope of pediatric epidemiologic research also expanded to include research focused on not only genetic, but also environmental determinants of birth defects, environmental threats for pubertal onset and progression, and the effects of infertility treatment on children's growth and development through three years of age. In addition, the PRB's research has expanded to include adolescent behaviors and, in the near future, will address the interplay among genes and adolescent behavior. The BBB, formerly the Biometry and Mathematical Statistics Branch, was renamed in 2008 in response to an updated research mission and scope that includes both biostatistical and bioinformatics research domains. Division researchers remain committed to the dissemination and translation of their findings and regularly work with regulatory agencies, policy entities, or professional societies as appropriate.

As a part of its strategic planning, the Division has successfully completed recruitments for senior leadership positions (Division director and BBB chief) and has targeted biostatistical tenure-track investigators for hiring. As a part of its ongoing strategic planning, the Division will recruit tenure-track investigators for its EB and PRB; their expertise will complement the Branches' new research initiatives focusing on utilizing a life-course epidemiologic design to understand the genetic-environmental determinants underlying the transition of gestational diabetes to Type 2 diabetes, and the behavioral-genetic determinants of risky adolescent behavior. In addition, the Division will support the NIH's mentoring mission for its intramural components by continuing to recruit, train, and professionally place its fellows and summer interns; since the last report to the NACHHD Council, the Division has supported 71 fellows and 50 summer interns.

Like other NICHD intramural components, the Division undergoes a combination of internal planning and external review to determine its possible future research directions. Branches hold annual retreats to discuss research progress from the previous year, review the status of projects, and consider extending and adding to research topics. The Board of Scientific Counselors (BSC), a panel of external scientists who have expertise in topics related to the Division portfolio, reviews each investigator, Branch, and the Division as a whole every four years. The most recent Board review was held in 2008. The Division's senior leadership uses input from the BSC to finalize the Division's future research strategy and to be sure that it meets its overall mission inclusive of mentoring and professional service. The [*BSC Review, Progress, and Future Directions for the Division*](#) section of this report includes more detailed descriptions of this process and its results.

In sum, the Division is well prepared to meet the nation's growing need for public health research and to expand its program as this need continues to increase. The Division will continue to design research addressing critical data gaps, which impact the entire population and its special groups, while also continuing to develop its mentoring and professional service missions.

ABOUT THE DIVISION

HISTORY

The Division of Epidemiology, Statistics, and Prevention Research has had a longstanding presence within the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD), within the National Institutes of Health (NIH). It first appeared on the NICHD's organizational chart in 1967, only five years after the establishment of the Institute, as the Epidemiology and Biometry Branch and was renamed the Epidemiology and Biometry Research Program in 1970. In 1990, the Program was reorganized and renamed the Division of Prevention Research; in 1991, it became the Division of Epidemiology, Statistics, and Prevention Research. Dr. Mark Klebanoff served as the Division director until January 2008, when he returned to the Epidemiology Branch (EB) as a senior investigator. Dr. Germaine M. Buck

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Louis was appointed acting director on August 27, 2007, and accepted the permanent position as director on November 16, 2009.

MISSION AND SCOPE

The Division has an ambitious three-fold mission, to:

- Design and conduct original and collaborative research;
- Help develop and mentor the next cadre of public health and clinical researchers; and
- Proactively provide professional service throughout the NIH, other federal agencies, and professional societies.

The Division designs research projects to address critical data gaps, particularly those relevant to the health and well-being of the public and its special populations, and utilizes novel methodologies, including those developed by the Division, to complete this work. The Division's research is often risky in nature in that it uses novel study designs and methodologies, which might not have been previously demonstrated for specific research questions.

Investigators identify critical data gaps for issues within the Division's mission and prioritize the selection of research questions for which innovative and often population-based study designs are deemed capable of answering mission-specific research questions. To this end, the Division's high-impact research is designed to fill critical data gaps and, thereby, move the science forward with the goal of improving the health of the population.

ORGANIZATION AND LEADERSHIP

Organizationally, the Division is one of two intramural divisions and reports directly to the NICHD Director. The Division comprises the Office of the Director; three research Branches: the Biostatistics & Bioinformatics Branch (BBB), the Epidemiology Branch (EB), and the Prevention Research Branch (PRB); a Computer Sciences Section (CSS), which provides onsite computing support services; and the Collaborative Studies Section, which includes the NIH-D.C. Initiative to Reduce Infant Mortality in Minority Populations, known as the D.C. Initiative. Although the D.C. Initiative is administratively housed within the Division, it is an extramural cooperative agreement and is individually reviewed by the National Advisory Child Health and Human Development (NACHHD) Council.

Since the 2005 report to the NACHHD Council, the Division eliminated two sections, both within the EB. Specifically, the Pediatric Epidemiology Section and the Pediatric Infectious Disease and Vaccinology Section were eliminated in 2006 due to vacancies or the reprioritization of research areas. Currently, no Branch includes any sections.

Leadership and administrative responsibilities for the Division rest with the Division director working in collaboration with the senior Division leadership, which includes all Branch chiefs, the CSS chief, and the chief of the D.C. Initiative; the senior leadership are assisted by the

Division's program analyst. Administratively, the Branch chiefs report to the Division director, who reports directly to the NICHD Director. The Division follows intramural procedures for recruitment, tenure, promotion, and review of scientific personnel; likewise, all research conducted by Division members is intramural.

Organization and Leadership within the BBB

Although the Branch chief has overall responsibility for the leadership of the Branch, investigators are independent statistical scientists responsible for formulating an independent methodological research program, inclusive of collaborations with EB and PRB scientists on the design and analysis of Division studies.

The Branch has placed considerable emphasis on creating an environment that fosters the development of new statistical methodology to meet the research mission of the Division and the Institute. Most of the independent research conducted by BBB investigators is focused on solving important analytical challenges in design and analysis that will lead to progress in the fields of reproductive, perinatal, and pediatric epidemiology, as well as in child and adolescent health behavior. The Branch has also expanded its research portfolio to include additional research topics, including an expanded focus on methodology for longitudinal and correlated data, the analysis of biomarker data, the analysis of time-to-event data, the analysis of genetics data, and the analysis of data from clinical trials, all important for the Division's mission.

Organization and Leadership within the EB

Organizationally, the EB comprises 11 full-time employees, 10 Intramural Research Training Award (IRTA) fellows, and one neonatology fellow. The Branch chief is administratively responsible for the Branch and reports directly to the Division director. Dr. Mary Hediger was appointed as acting Branch chief in 2009.

Organization and Leadership within the PRB

Although the Branch chief has overall responsibility for the conceptualization of the PRB program of research, investigators are independent and fully responsible for the conduct and management of the collaborative studies they lead. Each PRB staff member, including senior staff and postdoctoral fellows, serves on one or more study teams based on his or her interests and skills. Some investigators are linked primarily to one area of research, while others work in several research areas. Authorship on publications and presentations is determined according to contribution and per standard publication requirements for authorship.

PERSONNEL

Currently, the Division includes 29 full-time positions, including 11 senior (tenured) investigators, five tenure-track investigators, four staff scientists, one biologist, two research fellows, and six individuals in other support positions as listed in [Table 1](#). In addition, seven onsite contractors provide programming support. Detailed descriptions of personnel backgrounds are available in [Appendix A](#).

Since the last report to the NACHHD Council, there were two personnel changes in the Office of the Director. First, Dr. Mark Klebanoff was reappointed from Division director to senior investigator in the EB as of January 2008. Second, Ms. Adrienne Lonaberger was hired as a secretary to replace Ms. Kaye Beall, who left the Division in 2006. In 2009, Ms. Lonaberger's position was revised as a program analyst to be consistent with her roles and responsibilities in aiding the Division.

Within the BBB, leadership and staffing changes were made in keeping with the formal restructuring of the Branch for its updated research focus. These include: the reappointment of Dr. Kai Yu from Branch chief to senior investigator in 2008; the appointment of Dr. Paul Albert as senior investigator and Branch chief on July 6, 2009; the appointment of three tenure-track investigators, Drs. Zhen Chen, Rajeshwari Sundaram, and Zhiwei Zhang, in 2009, 2006, and 2009, respectively, following a full and open national search; and the appointment of Dr. Sung-Duk Kim as a research fellow in 2008. In addition, Dr. Aiyi Liu was promoted to senior investigator in 2007.

There were also a number of personnel changes within the EB, with a net loss of one position, which was reallocated to the BBB as a part of its restructuring. Five new investigators—Drs. Ondine von Ehrenstein, Cuilin Zhang, Jagteshwar (Una) Grewal, Neil Perkins, and Zhen Chen—joined the Branch in 2007-2008 following full and open national and international searches. Dr. Mark Klebanoff returned to the Branch as a senior investigator after stepping down as Division director in January 2008. Dr. von Ehrenstein left the Branch for a position at the University of California, Los Angeles in September 2008. In addition, Drs. Jun Zhang and Enrique Schisterman were promoted to senior investigators in 2005 and 2007, respectively.

The PRB has had three changes in personnel during the reporting period: the appointment of Dr. Ronald Iannotti to staff scientist in 2005; the appointment of Dr. Marie-Claude Ouimet to research fellow in 2008, and her departure for a faculty position in 2009; and the appointment of Dr. Jing Wang as research fellow in 2009.

BUDGET

Each year, the senior Division leadership prepares budget requests following extensive planning at both the Branch and Division levels. The Division manages both an operating budget and a research contract budget. The operating budget covers the day-to-day costs, travel, training, seminar speakers, and sabbaticals for visiting faculty, computing resources, and other one-time purchases (e.g., furniture, laptops). [Table 2](#) presents the Division's operating budget by year and by Branch and reflects approximately a 3-percent reduction from \$812,403 in 2005, to \$789,467 in 2009, despite a small increase in the number of full-time equivalent positions. Of note are the two new positions, including a new Branch chief and tenure-track investigator, for the BBB as a part of its restructuring.

The major source for the Division's research is its research and development (R&D) contract budget. All Division components follow the same process for obtaining research contracting support, beginning with the preparation of a concept proposal for approval at the Branch,

Division, and extramural levels followed by presentation at the Institute's annual contract-planning process meeting. In prioritizing new research, the senior Division leadership weighs four factors: scientific rigor, cost, investigator's status with regard to funding, and degree of collaboration. [Table 3](#) presents the distribution of the Division's annual R&D contracting budget by Branch and investigator for the period of review, 2005-2009. These figures present merely a "snap shot" of funding because some of the Division's current research was awarded prior to 2005, but still has costs in the out years under review, while other research is just beginning and extends beyond 2009. The Division's research contract budget totals approximately \$15 million annually. As a result of judicious staff management, the Division has not experienced cost overruns in the successful completion of its research since its last report to Council.

The Division also supports a biospecimen repository and onsite programmers/statisticians, particularly when designing onsite data management systems for research contracts. With regard to the latter, the distribution of use by Branch is as follows:

- The BBB utilizes approximately 5 percent of the support budget.
- The EB utilizes approximately 64 percent of the support budget.
- The PRB utilizes approximately 30 percent of the support contract.
- The Division has a combined total of 60,745 contracting hours for data management, programming, and statistical support.

A third Division-wide resource became available in 2008 with the awarding of an indefinite delivery/indefinite quantity (IDIQ) contract for data coordination. This IDIQ minimizes the number of data-coordinating center contracts required by the Division. Specifically, the IDIQ centralizes the Division's Web-based data management contracts into one. Moreover, the Division analyzes all data onsite and no longer outsources these activities, resulting in cost reduction. Currently, the Division is working to establish an IDIQ laboratory support contract as an expeditious and cost-effective means of analyzing newly collected and banked biospecimens.

RESEARCH MISSION

The overarching mission of the Division reflects that of the overall NIH intramural research mission, including original research, mentoring, and professional service. Within the context of research, each of the Division's three Branches adapts this mission to reflect both its own expertise and that of the Division. For instance, the BBB conducts research in statistical methodology relevant to the Institute's mission, while also engaging in collaborative etiologic research or randomized clinical efficacy or public health intervention trials. The research mission of the EB is to design and implement original investigator-initiated research focusing on reproductive, perinatal, and pediatric health endpoints to identify etiologic mechanisms, at-risk subgroups, and interventions aimed at maximizing health and preventing, diagnosing, and/or treating disease. Similarly, the research mission of the PRB is to conceptualize, design, and conduct research to identify the determinants of child and adolescent health behavior, and to test the efficacy and effectiveness of educational, behavioral, and environmental strategies for improving or protecting child and adolescent health.

All Division investigators are charged with designing research that typically cannot be done within the context of a grant mechanism, either because of its given scope and complexity, or because of the required commitment of resources to address critical data gaps. Much of the Division's research involves prospective cohort studies with longitudinal data capture and randomized clinical or intervention trials. This research is further supported by the considerable biostatistical expertise in experimental or prospective longitudinal observational designs.

During the reporting period, noteworthy research accomplishments include 444 refereed publications in high-impact journals, including 36 items in press. Of this total, 252 were contributed by the EB, 104 by the PRB, 77 by the BBB, and 11 by the Office of the Director. The following section highlights key research findings for each Branch and area of research and includes examples of their translations for targeted audiences. A more complete description of each Branch's mission and research accomplishments is provided in the individual Branch sections and in [Table 2](#).

Notable Research Accomplishments from the Division

BBB NOTABLE RESEARCH ACCOMPLISHMENTS

Since 2005, BBB investigators have accomplished the following:

- Developed statistical models for analyzing menstrual cycle data, which are instrumental in understanding the effect of environmental/dietary factors on changes in the dynamics of progesterone level during the menstrual cycle (Albert & Hunsberger, *Biometrics*, 2005)
- Developed methods to analyze randomly truncated data based on a proportional odds model, which provides useful alternative to the Cox's model (Sundaram, *Journal of Statistical Planning and Inference*, 2009)
- Developed a joint model of longitudinal intercourse behavior and fecundity to allow for studying the association between patterns of intercourse and time to conception, while also accounting for known risk factors for conception (Sundaram et al, *Biostatistics*, 2009)
- Developed methodology for combining multiple biomarkers to improve diagnostic accuracy using Receiver-Operating Characteristic (ROC) curves (Liu et al, *Stat Med*, 2009)
- Developed new methodology for testing genetic association with triads, that is, case children along with their parents (Troendle et al, *Ann Hum Genet*, 2009)
- Developed new methodology for obtaining exact simultaneous confidence intervals in a random effects model (Wu et al, *J Stat Plan Inference*, 2009)

EB NOTABLE RESEARCH ACCOMPLISHMENTS

Since 2005, EB investigators have had numerous accomplishments related to different subcategories of epidemiology.

REPRODUCTIVE EPIDEMIOLOGY

- Findings from a randomized clinical trial demonstrated that misoprostol is an inexpensive yet efficacious and safe alternative to dilation and curettage for the medical management of miscarriage. The results of this trial offer women an inexpensive (approximately \$1.00 U.S.)

non-surgical option for the management of miscarriage; this outcome could prove particularly critical for countries with limited surgical services (Zhang et al, *NEJM*, 2005).

- Investigators delineated the relation between biomarkers of oxidative stress (e.g., F2I, TBARS, and PON) and hormones (e.g., E2, PG, LH, FSH, and SHBG). In particular, this work identified associations between F2I and all hormones indicative of a role for oxidative stress in menstrual cycle function. Increased levels of endogenous estrogens were associated with an improved lipid profile during the luteal phase, supporting a recent finding from the Women's Health Initiative (Browne et al, *Clin Chem*, 2008; Gaskins et al, *Am J Clin Nutr*, 2009).
- Researchers identified specific polychlorinated biphenyl congeners and other persistent environmental chemicals with purported estrogenic or anti-estrogenic biologic activity as potential reproductive toxicants, as measured by diminished fecundity and endometriosis. This finding generates evidence for regulatory agencies responsible for classifying chemicals (Buck Louis et al, *Hum Reprod*, 2009).

PERINATAL EPIDEMIOLOGY

- Circulating levels of soluble endoglin and ratios of sFlt-1/PlGF herald the onset of preeclampsia. This finding prompted several large pharmaceutical companies to implement projects aimed at developing fast and accurate clinical tests for the quantification of sFlt-1, placental growth factor, and soluble endoglin to aid in the diagnosis of preeclampsia (Levine et al, *NEJM*, 2004 & 2006).
- Weekly injections of 17 alpha-hydroxyprogesterone caproate (17P) blunted the rise in maternal salivary concentration of estriol that normally precedes the onset of labor. This research provides new data on the previously unknown mechanism by which this drug prevents the recurrence of preterm birth (Klebanoff et al, *Am J Obstet Gynecol*, 2008).
- Research evidence confirmed that the vast majority of gestational diabetes could be prevented by adopting a healthier lifestyle, including a body mass index of less than 25 kg/m², a diet high in cereal fiber and low in glycemic load, engaging daily in 30 minutes of moderate-to-vigorous physical activity per day, and not smoking cigarettes (Zhang C et al, *Arch Intern Med*, 2006).

PEDIATRIC EPIDEMIOLOGY

- Evidence indicated that maternal alcohol intake during the peri-conceptional period increased the risk for conotruncal heart defects, neural tube defects (NTDs), and multiple cleft lip with or without cleft palate in infants (Grewal et al, *Birth Defects Res*, 2008).
- Researchers found no evidence to support earlier reports that eye malformations are a good way of identifying children with heavy prenatal alcohol exposure because all affected children had fetal alcohol syndrome (Flanigan et al, *J Pediatr*, 2008).
- Investigators found evidence to suggest that gluten-/casein-free diets negatively impact growth and maturation of boys with autism or autism spectrum disorders (ASDs), calling into question the purported and as yet unproven efficacy of such diets for affected children. Clinicians are being advised to discuss with parents the possibility of decreased bone development and the potential for an increase in the risk for fractures in the context of a risk-

to-benefit ratio in treating autism or ASDs with a casein-free diet (Hediger et al, *J Autism Dev Disord*, 2008).

- Formal swimming lessons conferred an 88-percent reduction in drowning risk among 1- to 4-year-old children (Brenner et al, *Arch Pediatr Adolesc Med*, 2009). This finding prompted the American Academy of Pediatrics (AAP) to reevaluate its policy statement regarding swimming lessons for children younger than five years of age; the new policy statement is currently under embargo.

METHODOLOGIC EPIDEMIOLOGIC RESEARCH

- Investigators developed statistical methods for obtaining unbiased estimates of potential discriminators of disease when using biomarkers (Perkins et al, *Stat Med*, 2009).
- Researchers developed a new cost-effective study design—pooled-unpooled hybrid design—that corrects for measurement error and limits of detection without the need for replications (Schisterman et al, *Stat Med*, 2009).

PRB NOTABLE RESEARCH ACCOMPLISHMENTS

PRB investigators have had multiple accomplishments related to prevention of risk or disease.

YOUNG DRIVERS

- Evidence showed that both male and female teenagers drive significantly faster and closer to the vehicle ahead when in the presence of male teenage passengers (Simons-Morton et al, *Accident Analysis Prevent*, 2005).
- Evidence indicated that teenagers whose parents set stricter limits on driving privileges early in licensure engaged in less risky driving and experienced fewer violations and crashes than teenagers whose parents set few limits on driving (Simons-Morton, *J Safety Res*, 2007).
- PRB investigators designed the *Checkpoints Program* to encourage parents of newly licensed teenage drivers to adopt a parent-teen driving agreement and to set limits on their teenagers during the early months of licensure, when driving skills are rapidly developing. Evidence from three randomized trials demonstrated the Program's effectiveness in reducing crashes (Simons-Morton et al, *Am J Prev Med*, 2008). Currently, the Automobile Association of American (AAA) and the state of Michigan are conducting a statewide dissemination study, which may result in translation of the program nationally.
- Research showed that novice teenager drivers in families exposed to the *Checkpoints Program* engaged in less risky driving and had fewer traffic violations than teenagers randomized to the control group (Simons-Morton et al, *Accident Analysis Prevent*, 2006).

ADOLESCENT BEHAVIOR

- A comparison of alcohol and marijuana use among tenth graders in the United States, Canada, and the Netherlands—three countries with different policies—found that U.S. adolescents drank less, but smoked more than did Dutch adolescents (Simons-Morton et al, *International Journal of Drug Policy*, 2009).
- The first national study of cyber bullying found that parent and peer support moderated the prevalence of bullying and victimization (Wang et al, *J Adoles Health*, 2009).

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- Evidence showed that sedentary behavior—independent of obesity—is negatively associated with multiple health outcomes, such as health status, quality-of-life, fewer health complaints, and avoiding substance use (Iannotti et al, *Inter J Pub Health*, 2009).

FAMILY MANAGEMENT OF CHILDHOOD DIABETES

- Adolescents with Type 1 diabetes experienced improved glycemic control when they participated in interventions delivered by trained non-professionals using applied problem-solving skills to address self-selected adherence behaviors (Nansel et al, *Diabetes Care*, 2009).
- Research demonstrated a bi-directional relation between parent-child conflict and diabetes control—that is, parent-child conflict contributed to poorer control, and poorer control contributed to greater parent-child conflict (Wysocki et al, *J Pediatr Psych*, 2009).
- Investigators found evidence suggesting that contemporary diabetes management regimens may inadvertently contribute to less healthful eating behaviors (Mehta et al, *Diabetes Care*, 2009).

MENTORING MISSION

The Division's exemplary commitment to mentoring includes a consistently strong trajectory of recruiting, mentoring, and placing fellows and interns in career-appropriate positions concurrent with the overarching goal of preparing them for careers as independent investigators.

With regard to notable mentoring accomplishments since 2005, the Division has mentored:

- 71 IRTA fellows, representing 48 different academic institutions, including two in the Office of the Director, eight in BBB, 36 in EB, and 25 in PRB
- Three neonatology fellows from the U.S. Navy within the EB, and two students in the Office of the Director
- 50 Summer Intern Program interns, representing 35 academic institutions, including nine in BBB, 30 in EB, and 11 in PRB

Another notable mentoring accomplishment is the establishment of the NICHD/Institute of Human Development, Child, and Youth Health (IHDCYH) Summer Institute for Reproductive and Perinatal Epidemiologic Research, managed through the EB since 2005. This one-week intensive summer course annually selects 20 doctoral students or clinical fellows interested in a career in reproductive or perinatal epidemiology. The faculty comprises Drs. Germaine Buck Louis, Mary Hediger, Mark Klebanoff, Enrique Schisterman, and Jim Zhang from the NICHD and Drs. K.S. Joseph, Michael Kramer, and Robert Platt from the IHDCYH. Now in its sixth year, the Summer Institute is highly regarded in the field as a competitive training program. The Institute has graduated 100 student-graduates, both domestic and foreign. After completing the Summer Institute, many participants apply for IRTA positions with the NICHD or for training positions supported by NICHD T32 grants.

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In addition, the Division—again through the EB—is involved in a short methods course for students, fellows, and attendees offered at the annual meeting of the Society for Pediatric & Perinatal Epidemiologic Research.

Division investigators also work closely with interns even after they leave the Division to help ensure their work is published, thereby, providing a rounded internship experience. Since 2005, seven of the Division's IRTA fellows (one from BBB, five from EB, and one from PRB) have received national awards for their research accomplishments, as noted in [Appendix E](#).

The Division and Branches are proud of their mentoring accomplishments and recognize that they could not complete their work without their many fellows and interns. See [Appendix B](#) for a complete list of fellows and interns.

PROFESSIONAL SERVICES MISSION

Division members also provide professional service in various venues and capacities, including (but not limited to) service on expert/advisory panels for:

- The National Academies and other research or regulatory entities;
- Other NIH Institutes' Boards of Scientific Counselors and committees;
- Executive leadership positions for professional societies; and
- Boards of directors of non-federal research entities.

In addition, Division investigators are professionally active on several levels, including (but not limited to): service on editorial boards for the highest impact statistical, epidemiologic, and health behavioral journals, such as *American Journal of Health Promotion*, *American Journal of Epidemiology*, *Biometrics*, *Epidemiology*, *Health, Education & Behavior*, *Paediatric & Perinatal Epidemiology*, and *Statistics & Medicine*; elected leadership roles for professional societies; and appointments to scientific advisory panels or other expert panels.

The Division remains committed to its professional services mission and continually engages in strategic planning to ensure its competitive stature for research excellence in the context of meeting its broader mission. See [Appendix D](#) for a complete listing of Division and Branch staff professional service activities.

OTHER INFORMATION ABOUT THE DIVISION

Division staff are very active in terms of their publishing in scientific and peer-reviewed journals. [Appendix C](#) provides bibliographic information for publications from Division staff. A number of Division investigators have received awards and honors related to their research, mentoring, or professional service. For a complete listing of staff awards and honors, visit [Appendix E](#).

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In addition, Division investigators are often invited to give scientific presentations, organize symposia, and participate in national and international meetings. [Appendix F](#) lists these types of activities for each member of the Division.

BIostatISTICS & BIOinformatics BRANCH (BBB)

MISSION AND SCOPE

The mission of the BBB is to:

- Conduct both collaborative and methodological research relevant to the mission of the Division and the Institute;
- Provide statistical training in areas of statistical research that will advance the Division's and Institute's research programs; and
- Serve as a resource for the Division, the Institute, the NIH, and related professional organizations.

The research component of the BBB mission is multifaceted. First, providing first-rate statistical collaboration requires understanding of the scientific issues, as well as an understanding of state-of-the-art statistical methodology relevant to the scientific problem and the ability to implement this methodology. Thus, investigators within the Branch need to play a role in all aspects of study design and implementation, from conception and design, to monitoring study progress, to statistical analysis, and eventually to writing study manuscripts. Second, the Branch develops new statistical methodology for designing and for analyzing data from these studies. Ideally, much of the independent research of BBB investigators is directly motivated by methodological problems encountered in its collaborative research. The most important statistical methodology is developed through a synergistic collaboration between Division investigators and statistical investigators within the BBB. Third, investigators within the Branch take a leadership role within the Division and the Institute to develop efficient design and analysis strategies for population- and laboratory-based studies. In some sense, this last role is the most difficult because it requires investigators to anticipate future technical tools and research directions in formulating these new methodological strategies.

The Division's research portfolio is necessarily diverse, ranging from longitudinal cohort studies and genetic epidemiology studies within the EB to naturalistic driving studies, intervention studies, and surveys within the PRB. This breadth presents both exciting opportunities and challenges for developing a first-rate biostatistics group within the Division. To address the broad range of studies, the Branch has the opportunity to develop new statistical methods in a wide range of areas, including longitudinal data analysis, survival data analysis, statistical genetics, survey sampling, and the analysis of biomarker data. These new methods can be developed using exciting and "fresh" data sources available from Division studies. Likewise the Division's diverse research portfolio can also pose challenges because the Branch must ensure that its independent methodological research remains focused and does not become too diffuse.

The Branch's expertise plays a critical role in assuring the high quality of study design and analysis techniques for all Division studies. With increased use of biomarkers to assess genetics, environmental exposures, and disease outcomes, the use of complex statistical methodologies for the appropriate design and analysis of data will become increasingly important. For example, the type of longitudinal “-omics” data being collected in many Division studies provides a unique opportunity for the BBB to develop innovative new statistical methodology for study design and for analyses of longitudinal “-omics” data. These new methods will help investigators—both those within the Division and within the research community as a whole—design more efficient studies, which can obtain the most information using a minimum amount of resources.

RESEARCH MISSION

As discussed earlier, leading biostatistics groups integrate independent methodological research with collaborative research. Ideally, this integration leads to a synergistic relationship between both types of research, whereby methodology is initially motivated by collaborative research, and the resulting methodological research then provides the tools to further advance the collaborative research. During the past five years, BBB investigators have made important contributions in the analysis of diagnostic testing, joint modeling of longitudinal and time-to-event data, analysis of biomarker data, and statistical genetics. For instance, BBB investigators developed a joint model for longitudinal behavioral measurements and time-to-pregnancy that allows researchers to make valid inferences about the association between both processes. BBB investigators also developed approaches for efficiently modeling the pattern in longitudinal biomarker data collected during the menstrual cycle. Both of these approaches are currently being applied in research studies for the Division.

[Table 4](#) provides a brief overview of the investigator-initiated research projects within the BBB portfolio. The Branch's staff are listed in [Appendix A](#), and its fellows and interns are listed in [Appendix B](#). BBB staff publications are listed in [Appendix C](#), and staff professional service, awards, and symposia/presentations are listed in [Appendix D](#), [Appendix E](#), and [Appendix F](#), respectively. Although the topics of the Branch's methodological research are necessarily broad, there are general themes to its independent methodological research. The following sections describe the Branch's four general methodological themes and some of the activities within each theme.

RESEARCH ON LONGITUDINAL DATA ANALYSIS

Many of the Division's studies are longitudinal and involve sampling frameworks, such as schools, families (parent-child triads), couples, maternal/fetal pairs, and individuals. Longitudinal studies have inherent methodological challenges over time, including the problems of attrition, difficulties in making statistical inference when data are correlated, and difficulties in characterizing complex longitudinal patterns. Many of the Branch's independent research projects address one or more of these issues in the context of substantive problems related to one

or more of the Division's studies. Some examples of the BBB's research on longitudinal data analysis are briefly described below.

Modeling Longitudinal Menstrual Cycle Data

The BioCycle Study, conducted by the EB, is a longitudinal cohort study aimed at determining the association between oxidative stress levels and endogenous reproductive hormone levels. Characterizing the longitudinal profiles of multiple biomarkers over the course of the menstrual cycle is a challenging methodological problem. BBB investigators, along with those in EB, are working to develop new model classes for characterizing menstrual cycle variation in longitudinal biomarkers when measurements occur at irregular time points. The length of the menstrual cycle may be related to the underlying cyclic patterns of important hormone levels. BBB and EB investigators are currently seeking new approaches for jointly modeling the length of a menstrual cycle and the underlying cyclic pattern of important biomarkers. These joint models will help investigators better understand the interrelationships between hormonal patterns and the length of the menstrual cycle, and to make valid inferences about the hormonal patterns during the menstrual cycle when measurements are at fixed, irregular time points during the cycle.

Joint Modeling of Time-to-Event and Longitudinal Data

Understanding the relationships between longitudinal data and the time to an event (such as time to ovulation or time to pregnancy) poses difficult methodological challenges. The longitudinal data are often subject to measurement error, which must be accounted for in the analysis. Joint modeling of event-time and longitudinal data is one approach for dealing with the measurement error problem. BBB investigators are currently working on approaches for jointly modeling the two processes when: the longitudinal data are binary indicators of behavior, such as intercourse, in a time-to-pregnancy study; and the longitudinal data are high-dimensional continuous variables, such as a multiplex panel of cytokines in a longitudinal biomarker study. These statistical methodologies will not only be important tools for Division studies, such as the Longitudinal Investigation of Fertility and the Environment (LIFE) Study and the BioCycle Study, but will also be applicable across a wide range of applications in epidemiologic and clinical research.

Modeling Longitudinal Data with an Informative Number of Measurements

Most methodology for analyzing longitudinal data assumes that the number and timing of follow-up measurements are not related to the underlying longitudinal response for an individual. In many Division studies, follow-up measurements are based on whether a follow-up visit is clinically indicated. For example, in studying the trend of fetal growth in terms of body weight, normal fetuses (those with normal body weights) might get fewer ultrasound tests than abnormal fetuses (those with large or small body weights). As a result, normally growing fetuses might contribute fewer observations (i.e., ultrasound readings) than abnormally growing fetuses. Thus, a standard approach to modeling fetal weight that ignores this informative number of ultrasound readings would be biased. Any accurate analysis approach has to properly account for this informative observation problem. The PRB longitudinal trial of behavioral intervention for Type 1 diabetes provides another example of this "number of measurements" problem. In this case, the number of follow-up visits varies across individuals and is determined by usual care.

BBB investigators are currently developing new statistical methods that account for this type of observation process.

Analyzing High-Dimensional Continuously Collected Longitudinal Data in Small Samples

This research is motivated by the Naturalistic Teenage Driving Study, led by the PRB with collaborators at the Virginia Tech Transportation Institute. The study follows 41 drivers during the first 18 months of independent, licensed driving using an in-vehicle data-recording system installed in participants' vehicles. The instrumentation includes accelerometers, cameras, Global Positioning Systems (GPS), front radar, and a lane tracker. The study has produced a rich set of data, which could shed light on many interesting scientific questions, such as whether or how the teenagers' driving performance varies over time, and whether poor driving performance could predict a crash. Because of the extensive observations on a small number of teen drivers, the analysis of these data poses unique statistical challenges. Synthesizing the large amount of data poses some of the same challenges encountered in analyzing “-omics” data. For example, analyzing the extensive information collected on each of potentially thousands of distinct car trips over an 18-month period is similar to analysis techniques for high-dimensional genomic data. BBB investigators are exploring new statistical approaches for making inferences in these types of situations.

RESEARCH ON ANALYZING TIME-TO-EVENT DATA

An important analytical issue for many Division studies is the characterization of time to an event. Many studies include repeated events (i.e., time to pregnancy, habitual pregnancy loss), and it is important to examine how various factors, such as environmental factors, affect these event times. Standard statistical methods in survival analysis, when the event time is death or the occurrence of disease, are well developed. However, time to pregnancy and other outcomes related to maternal and child health pose new analytic challenges. For example, unlike traditional survival analysis, time-to-pregnancy analysis must account for the fact that there is no risk for pregnancy without intercourse. Further, approaches for modeling time to pregnancy must account for the fact that a proportion of women will not become pregnant, regardless of number of attempts or duration of trying. The BBB is uniquely poised to address these issues. Examples of specific research in this area are included below.

Statistical Modeling of Human Fecundity

Reproductive epidemiologists are increasingly interested in ascertaining the influence of environmental exposures on reproductive health of humans; however, research is not readily amenable to experimental designs. One quantity of considerable interest—human fecundability—has necessitated development of better statistical methods and models for its study. Human fecundability is measured through the probability of conception in a menstrual cycle for a couple who is having regular intercourse and is not using contraception. Because of the inherent hierarchical data structure and measurement error involved in various quantities, such as day of ovulation, identification of “fertile window” length, and other biological quantities (some of them unmeasured) with considerable impact on conception and on probability and the time to conception, the statistical methods required are very specific to this area of research. BBB investigators have developed methods that address joint modeling of

longitudinal intercourse data and time-to-pregnancy data. The Branch has also studied issues related to incorporating chemical mixtures, a process which results in highly correlated covariates, into survival models to assess the effects of environmental exposures on time to pregnancy. These methods have applications for various prospective pregnancy cohort studies, such as the LIFE Study, that involve preconception recruitment of women or couples.

Statistical Methods in Survival Analysis

Developing new methods for survival analysis is an important and dynamic biostatistics research area. Although survival is not usually an endpoint in Division studies, many survival analyses techniques can be adapted to analyzing time to a particular event, such as time to pregnancy, time to an important milestone in fetal or child growth, gestational age, time to ovulation, or time to a crash in the teen driving studies. Adapting and developing new statistical methods for survival analysis that are applicable to the type of event times related to child and maternal health is complex and complicated. BBB investigators are working to create new methods of analyzing recurrent events (such as the timing of multiple pregnancies), correlated-survival data (such as time to ovulation when multiple cycles of the same women are observed), multistate events (such as time to different milestones in child development), and event-times with competing risks (such as time-to-poor delivery outcome).

ANALYSIS OF BIOMARKER DATA

Methodological issues inherent to designing and analyzing studies with biomarker measurements occur in most of the Division's studies. These issues often provide the source for many of the independent methodological research projects in the Branch. Some of this research is described below.

Design and Analysis of Studies Using Pooled Biomarkers

BBB investigators, in collaboration with EB investigators, are designing new ways to pool biomarker specimens in epidemiologic and clinical studies. Specifically, they are developing approaches for cohort studies in which the exposure is based on pooled biomarker samples. Design and analysis approaches for longitudinal studies, such as BioCycle, in which the longitudinal outcomes may be pooled are also under investigation. These new analytic approaches for both the design and statistical analyses will provide investigators with the ability to extract more information with fewer resources in subsequent studies.

Analyzing Data with Detection Limits

BBB investigators, again in collaboration with EB investigators, are developing new methods for analyzing both exposure and outcome data with detection limits, a particularly important issue for environmental epidemiologic research in which environmentally relevant exposures are at or below the laboratory detection limits. Methods research, much of it led by the Division, revealed that automatic substitution of values below the limits of detection introduces bias when estimating health effects. BBB investigators are developing new semi-parametric methods, which will rely on fewer assumptions to make statistical inferences in this situation.

New Methods for Assessing Inter-Rater Agreement and Diagnostic Accuracy

One important objective in many epidemiologic and clinical studies is to assess the agreement between different categorical or ordinal ratings. The “kappa coefficient” is a widely used index for inter-observer agreement that is more appealing than percent-agreement because it corrects for the proportion of agreement expected by chance. Studies often collect longitudinal assessments of agreement. BBB investigators are developing new methodology for assessing agreement of longitudinally collected ratings or scores in these situations. In addition to assessing agreement, researchers are often interested in assessing the accuracy of ratings or tests when there is no “gold standard” test available. Other new methods, developed by BBB staff, include those for making inferences about the diagnostic accuracy of these tests when no such standard exists. In fact, many of the methods were developed from collaborative research in the Endometriosis: Natural History, Diagnosis, and Outcomes (ENDO) Study, which is focused on comparing and evaluating different measures for diagnosing endometriosis in the absence of a gold standard.

ANALYSIS OF GENETICS DATA

The analysis of genetics data is an active area of biostatistics research and presents unique opportunities and statistical challenges, especially when dealing with data related to birth defects. For example, Division studies often have genetic information on a particular child as well as on both parents (triads). Incorporating all of this genetic information into the analysis is very complex. Some examples of efforts within this topic are described below.

Multiple Comparisons in Genetic Testing and Methods of Genetic Association Testing

BBB investigators are addressing the need for new approaches to account for multiple comparison problems inherent in the large number of statistical tests conducted in many genetic epidemiology studies. For example, this methodology will be important in analyzing genetic association studies with large numbers of single nucleotide polymorphisms (SNPs) for studying genetic effects on NTDs.

BBB investigators are also working on new approaches to testing for genetic associations in genetic epidemiologic studies of triads (case child and parents). These methods aim to exploit the triad structure, providing a more powerful test of genetic association compared to standard genetic association tests. These new approaches were directly motivated by BBB staff collaborations with EB investigators who are studying NTDs.

Statistical Methodology for Understanding Copy Number Variation

Copy number variations, the varying number of copies in small segments of chromosomes, are more useful for explaining larger phenotype variations than the commonly used SNPs. However, the actual copy numbers of chromosome segments are usually not directly observable; rather, some generated signal intensities are reflective of the underlying copy number state at each SNP. Statistical methods that infer the unobserved copy number state using observed signal intensities have been proposed for the study of unrelated individuals using hidden Markov models (HMM). Researchers also want to extend the existing approach to related individuals, such as family members. To address this issue, BBB investigators developed HMMs that can

incorporate Mendelian inheritance information among family members and, hence, can more accurately uncover the latent copy number states. These new approaches will be useful for analyzing genome-wide association studies (GWAS) in future Division and Institute studies.

Statistical Methods for Mendelian Randomization in Case-Control Studies

Given their susceptibility to confounding and reverse causation, the effects of intermediate phenotypes (e.g., fasting insulin levels) on disease (e.g., Type 2 diabetes) estimated from case-control or observational studies are often difficult to interpret. Mendelian randomization is a technique which adjusts for known or unknown confounding in a case-control setting by carefully selecting a gene as an instrumental variable in the causal pathway, and using the gene-phenotype association and gene-disease association to obtain a consistent estimate of the phenotype-disease association. BBB investigators, in collaboration with EB investigators, are developing statistical methodology that focuses on deriving Mendelian randomization estimates of phenotype-disease association for discrete disease outcomes and for various scenarios, such as multiple genes, multiple phenotypes, longitudinal phenotype data, and phenotype data with measurement errors.

EPIDEMIOLOGY BRANCH (EB)

MISSION AND SCOPE

The three-fold mission of the EB, consistent with that of the NIH intramural research program, is to:

- Design and conduct investigator-initiated original epidemiologic research focusing on reproductive, perinatal, and pediatric health endpoints with the goal of identifying etiologic mechanisms, at-risk subgroups, and interventions aimed at maximizing health and preventing, diagnosing, and/or treating disease;
- Provide service to the Division, Institute, NIH, Department of Health and Human Services, and the profession via consultation, collaboration, and assistance to advance the scientific discipline of epidemiology and the goals of the Institute; and
- Recruit highly qualified students and trainees at various stages of their professional careers to train them in reproductive, perinatal, and/or pediatric epidemiologic research.

RESEARCH MISSION

During the reporting period, the EB has continued its progress as a high-impact and productive intramural Branch dedicated to reproductive, perinatal, and pediatric epidemiologic research. The Branch designs both etiologic and clinical trials responsive to overarching critical public health and clinical data gaps using methodologies which cannot be done under a grant mechanism. In essence, the EB conducts risky, potentially high-impact research not suitable for support through an extramural grant. The Branch's research findings have implications for

public health and for clinical medicine, and investigators work to support the interplay between public health and public policy to the extent allowable for intramural investigators. The Branch continues to produce an extraordinarily large body of high-impact refereed papers; since the 2005 report to the NACHHD Council, the EB has published 265 such papers.

Branch members have conceptually overlapping research interests, but have varying expertise within a particular domain. [Table 5](#) provides a listing of the Branch's intramurally funded research, including its collaborations within and across Branches. The EB has eight active research contracts, of which, two will end in fiscal year 2010. EB staff are listed in [Appendix A](#), and its fellows and interns are listed in [Appendix B](#). EB staff publications are listed in [Appendix C](#), and staff professional service, awards, and symposia/presentations are listed in [Appendix D](#), [Appendix E](#), and [Appendix F](#), respectively.

A description of the accomplishments for each of the Branch's research projects follows, categorized by its three research domains—reproductive, perinatal, and pediatric epidemiologic research. The Branch also conducts methodological epidemiologic research largely focused on novel methodologies relevant for utilizing laboratory data in public health and clinical domains.

REPRODUCTIVE EPIDEMIOLOGIC RESEARCH

Reproductive epidemiologic research initiatives have as their overall goal the identification of the determinants of human fecundity and fertility irrespective of couples' pregnancy intentions. As such, the Branch conducts research focusing on: adiposity, fecundity and fertility, gynecologic and urologic health, and the prevention of miscarriage. Projects within these themes are outlined in [Table 5A](#) and are described below.

Adiposity: Genome-Wide Genetic Signals

Abdominal obesity is a principal component of the metabolic syndrome and is strongly associated with adverse metabolic profiles, such as systematic inflammation, insulin resistance, hyperglycemia, and dyslipidemia. Components of these profiles play important roles in the pathogenesis of many diseases, including unfavorable reproductive (e.g., polycystic ovary syndrome), perinatal (e.g., gestational diabetes, preeclampsia), and neonatal (e.g., macrosomia) outcomes. Additive genetic effects reportedly might account for 60 percent to 80 percent of the variance in abdominal adiposity, a finding that supports a genetic predisposition for this anthropomorphic state. Recent evidence suggests that abdominal adiposity, although correlated with overall adiposity, may have its own genetic architecture. Technologic strides in the development of genotyping technology and accompanying analytical methods now allow investigators to design whole GWAS for the identification of genetic signals for complex traits. However, the absence of data regarding the specific genes involved in producing abdominal adiposity serve as an impetus for the Branch's work in this area.

In collaboration with a multidisciplinary group of colleagues from the Harvard School of Public Health, Branch investigators are examining novel genetic signals associated with abdominal adiposity among women in the Nurses' Health Study (NHS), which began in 1967 to learn about the potential long-term consequences of oral contraceptive use. Using combined GWAS data

from three genome-wide scans (i.e., NHS, Diabetes Genetics Initiative, Finland-U.S. Investigation of Non-Insulin Dependent Diabetes Mellitus Genetics), researchers first identified a ranked list of important genome-wide signals of abdominal adiposity through *in silico* genotyping and meta-analytic procedures. Then, using 2,000 independent samples included in the NHS, they replicated and confirmed the top 150 SNPs from the ranked list in association with abdominal adiposity measurements. Through this collaboration, the Branch is able to leverage resources between the two institutions for the timely identification of genetic markers, which may be the basis of more focused etiologic research; at the same time, findings pertaining to gene-environment interactions may be informative about diet and lifestyle and, thereby, impact public health. Findings from this study will add to the knowledge about genetics and pathophysiology of abdominal adiposity. Plans for this study include finalizing data analysis, preparing papers, and investigating opportunities for follow-on studies using banked biospecimens or existing data.

BioCycle Study

The BioCycle Study was designed to assess the relationship between reproductive hormones and biomarkers of oxidative stress among premenopausal women. The study aims, in part, to address how methodologic variations in the timing of biospecimen collection during the menstrual cycle might account for the equivocal findings in the literature. BioCycle researchers collected multiple markers of oxidative stress, reproductive hormones, inflammation, and metabolism in a cohort of 259 women of reproductive age during the course of two menstrual cycles, with visits timed using fertility monitors. Additional information was obtained regarding lifestyle, perceived stress, diet, bone density, body hair patterns, and acne. Compliance with the protocol was high, with 87 percent of women completing at least seven or more of the 16 required visits.

Data analysis is underway, but several new findings have been reported:

- Results showed a significant positive association between F2-Isoprostanes (F2I), a marker of oxidative stress, and estrogen, raising questions about the longstanding belief that estrogen is a strong antioxidant;
- Researchers found an inverse association between estrogen and both total and low-density-lipid cholesterol, but a positive association between high-density lipids and estrogen; and
- There was an increased risk of anovulation among women who consumed at least 22 grams or more of fiber each day compared with women who consumed less.

A series of papers are in press or under review. During the next few years, data analysis will continue along with the preparation of papers and exploration of existing banked biospecimens for novel laboratory analysis.

Effects of Aspirin in Gestation and Reproduction (EAGeR) Trial

The EAGeR Trial is a multisite randomized clinical trial to assess the efficacy and safety of low-dose aspirin for the prevention of miscarriage among women with a previous pregnancy loss. Participating women are randomly assigned to one of two treatment groups, in which they receive a daily regimen of low-dose aspirin supplemented with folic acid or a daily placebo (folic acid alone). Women are followed for six menstrual cycles; those who become pregnant are followed through delivery. Data collection includes the completion of standardized

questionnaires and monthly urine and blood samples. Currently, 694 baseline visits have been conducted and 673 of the necessary 1,600 women (42 percent) were randomized at one of the following participating sites: Buffalo, New York; Denver, Colorado; Salt Lake City, Utah; or Scranton, Pennsylvania. The study is progressing with good adherence; 74 percent of participants report no medication lapses, and only 2 percent report missing more than five days of medication.

Future activities for this study include: continuing to monitor the progress of the study with specific attention to recruitment and retention efforts, and preparing for the completion of the study and implementation of the analytic plan trial results.

Endometriosis: Natural History, Diagnosis, and Outcomes (ENDO) Study

Approximately 10 studies have assessed persistent environmental chemicals in relation to endometriosis; equivocal findings make it difficult to interpret the strong experimental and *in vitro* research supporting a relationship between dioxin and like compounds and the development and severity of endometriosis. Research characterizing exposure by internal dose and disease status is a critical gap in knowledge. Other methodologic challenges include a population-based sampling strategy to minimize potential selection biases associated with convenience sampling. The ENDO Study utilized a matched-exposure cohort design to recruit women, aged 18 years to 44 years, from geographic areas with known environmental contamination who were undergoing laparoscopy to assess the relation between exposure to persistent environmental chemicals and the incidence and severity of endometriosis.

Overall, 69 percent of the 2,944 women scheduled for laparoscopies between 2007 and 2009 at participating clinical sites (affiliated with the University of California, San Francisco, and the University of Utah) were evaluated for eligibility before surgery. However, despite the minimal study requirements, the majority of women were ineligible largely due to age, a fact which underscores the potential role of selection bias for studies relying upon convenience sampling. Despite the intensity of the study design, 77 percent of eligible women enrolled in the operative cohort component of the study. In addition, researchers recruited approximately 129 similarly aged women living in the geographic area served by the clinical facilities to represent the unexposed cohort not having laparoscopy performed. Women with endometriosis will be compared with unaffected women in both the exposed (surgery) and unexposed (population) cohorts to assess the consistency and robustness of the findings.

To address potential methodologic limitations associated with a medical care-seeking population, a random sample of women in the operative cohort underwent magnetic resonance imaging (MRI) for the detection of endometriosis. This approach allowed study leaders to assess the study findings with respect to women who did not seek medical care for gynecologic reasons in the population cohort; all such women undergo MRI to detect endometriosis and to quantify total subcutaneous, superficial subcutaneous, deep subcutaneous, and intra-abdominal visceral fat content. These latter data are important for consideration of lipophilic chemicals and the predominantly peripheral (low waist/hip ratio) distribution of body fat among women with endometriosis.

ENDO Study researchers conducted in-person interviews with all women in the study, followed by an in-depth anthropometric assessment and collection of a blood and urine samples for toxicologic analysis. They also obtained approximately 5 grams of omentum fat from women in the operative cohort, to quantify chemicals, along with peritoneal fluid and endometrial biopsies for future biomolecular etiologic work, such as the EB's proteomics component. The study was successfully completed in September 2009. Results from toxicologic analysis and proteomics analyses of urine, fat, and peritoneal fluid are expected in April 2010, and September 2011, respectively. One Branch researcher and a biostatistical collaborator have designed a reliability study to formally assess clinical diagnosis of endometriosis using data from the ENDO Study.

Longitudinal Investigation of Fertility and the Environment (LIFE) Study

The relation between the environment, globally defined to include chemicals and lifestyle, and human fecundity and fertility remains understudied, particularly from a couple-based perspective, in which longitudinal data and biospecimens are captured across sensitive windows of human development. The LIFE Study was designed to address these critical gaps in knowledge and focuses on persistent organic pollutants, including: polychlorinated biphenyls (PCBs), organochlorine pesticides (OCPs), polybrominated diphenyl ethers (PBDEs), and perfluorinated (PFOA) chemicals, along with three heavy metals: lead, cadmium, and mercury. Many of these compounds are reported to adversely affect hormonal pathways via a number of postulated mechanisms and are commonly referred to as endocrine-disrupting compounds (EDCs); these EDCs are purported to interfere with the synthesis, secretion, transport, binding, action, or elimination of the body's natural hormones required for homeostasis, reproduction, development, or behavior. Utilizing a prospective cohort design with preconception recruitment of couples, the LIFE Study's goal is to empirically assess the relation between serum or urinary concentrations of PCBs, OCPs, PBDEs, and PFOAs and five sensitive endpoints of human reproduction and development—namely time to pregnancy, pregnancy loss, infertility, decrements in gestation, and decrements in birth weight.

Using population-based sampling frameworks, the LIFE Study successfully recruited 501 couples, who were planning pregnancy, from 10 counties in Texas and from four counties in Michigan that have documented aquatic environmental contamination. Couples completed baseline interviews, provided biologic specimens—including blood, urine, saliva, and semen—at windows critical to human reproduction and completed daily journals while attempting pregnancy. Women who became pregnant completed daily journals through gestational week eight, and then did monthly journals through delivery. In addition, women were instructed on the use of home fertility monitors, to track reproductive hormones (E₃G and LH), and of home pregnancy test kits. A very complex hierarchical data structure inclusive of chemical mixtures, lifestyle, and covariate data is being supported by biostatistical co-investigators in BBB. The LIFE Study is the only one of its kind worldwide and should answer critical data questions about parentally mediated conception determinants.

Although data analysis is just beginning, the LIFE Study has already demonstrated that:

- Prospective cohort study designs with preconception enrollment of couples, though challenging, are feasible and useful for finding couples planning pregnancy in the next few months at any point in time.

The information in this document is no longer current. It is intended for reference only.

- The home can be used as a lab for collecting blood, urine, saliva, and semen.
- Couples will comply with intensive data-collection protocols, including the completion of daily journals for up to one year.
- Attrition from the study is earlier and, thereby, limits the resources required for non-compliant couples.

Investigators are planning a study to assess the contribution of spermatozoal RNAs in relation to probability of human chorionic gonadotropin-confirmed pregnancy and pregnancy loss. This avenue of inquiry will allow researchers to assess a suite of biomarkers of male reproductive fitness and to determine the paternal contribution to conception probabilities.

Longitudinal Study of Vaginal Flora

The normal vaginal microenvironment is relatively homogeneous and dominated by several *Lactobacillus* species, which protect against overgrowth of endogenous bacteria, such as anaerobic Gram-negative rods, genital *Mycoplasma*, and *Gardnerella vaginalis*, and against infection by pathogens, such as *Neisseria gonorrhoeae*. These *lactobacilli* protect by producing hydrogen peroxide, lactic acid, and bacteriocins. Bacterial vaginosis (BV) is a condition of unknown etiology whereby the normal *lactobacilli* are reduced or eliminated, while a wide variety of other endogenous organisms overgrow. BV is the most common cause of vaginitis in women of reproductive age and accounts for approximately 40 percent of vaginitis cases. In a nationally representative sample, a vaginal Gram stain indicative of BV was present in 29.2 percent of reproductive-age women. In addition to being a source of minor morbidity, BV is consistently associated with a variety of serious adverse health outcomes, including spontaneous abortion, failure of *in vitro* fertilization, preterm delivery, postoperative gynecologic infections, pelvic inflammatory disease, and acquisition of other sexually transmitted infections, including HIV. Branch and Division investigators have pursued an active program of research to determine the etiology of this enigmatic condition. Little is known about how BV is acquired and maintained, or why this condition is more than twice as prevalent among African American women as among other women.

This study, conducted under contract with the University of Alabama at Birmingham, enrolled 3,620 non-pregnant women of reproductive age and followed them quarterly for one year. At each visit, investigators collected detailed information on behavioral, demographic, and microbiological factors to determine factors associated with the acquisition and maintenance of BV. The study was successfully completed in 2004. Since the Division's last report to the NACHHD Council, numerous publications have resulted from this study. Major findings include the following:

- Women who reported increased psychosocial stress had increased incidence and prevalence of BV.
- Women who used hormonal contraception (i.e., oral, dermal, or injectable) had reduced prevalence of BV mainly due to increased occurrence of spontaneous remission.
- Increased dietary fat intake was associated with increased prevalence of BV.
- Vaginal douching was associated with increased incidence of BV.

The information in this document is no longer current. It is intended for reference only.

- Having an African American male sex partner was associated with increased incidence of BV.

Future research developed within the EAGeR Trial will address the association between BV and anovulation, implantation failure, and pregnancy loss. A BV component is also incorporated into the Pathogenesis of Preeclampsia and Gestational Diabetes among Pregnant Women with Chronic Hypertension or Obesity Study, which will begin enrollment in fiscal year 2011. In the latter study, obese pregnant women will be evaluated in a special research clinic, beginning in their first trimester, continuing every four weeks until 28 weeks' gestation, and then every two weeks until 36 weeks' gestation. Collection of Gram stains at every visit enables detailed characterization of the spontaneous remission and recurrence of BV, and of whether remission or recurrence impacts the incidence of preterm birth.

PERINATAL EPIDEMIOLOGIC RESEARCH

The Branch conducts research on the perinatal period—defined as the interval before and after delivery irrespective of whether the labor was spontaneous or induced—and on gravid health status and obstetric management of the parturient woman, including health implications for both mothers and infants. Currently, the Branch has four avenues of research, described below. These activities are also listed in [Table 5B](#).

Consortium on Safe Labor

During the past half century, management of labor was typically guided by the Friedman curve, first established in 1955, which was based upon 500 parturient women at term and resulted in definitions for labor protraction (less than 1.2 cm/hour) and arrest (absence of cervical dilation within two hours). Despite the many changes in the obstetrical population and in obstetrical practice since the 1950s, these definitions remain standards in current obstetric practice.

The primary research aims of the Consortium on Safe Labor are to: describe contemporary labor progression in a contemporary population of U.S. women and establish a U.S. reference for labor progression; and determine the appropriate time for performing a Cesarean delivery among women with labor protraction and arrest. To establish new definitions for labor protraction and arrest, two important issues must be addressed. First, what is the average range of labor progression in the current obstetrical population? Second, is it safe (for mothers and fetuses) to allow women to labor longer? In such cases, severe adverse perinatal outcomes (such as neonatal asphyxia and seizures) are rare. A very large sample size ideally representative of current practice is required to provide a definitive answer to these questions. Branch investigators have designed a retrospective observational study encompassing perinatal registry data already collected by many hospitals in the United States to answer these questions with the goal of providing empirical evidence for clinical practice guidelines. Chart review was conducted when necessary to validate key study outcomes.

Data acquisition and management were successfully completed in 2009 and included data from 12 clinical centers across the United States, representing more than 200,000 deliveries. The primary study exposure was the duration of labor protraction (e.g., time since last vaginal exam

to the latest vaginal exam without perceivable cervical dilation), and the primary adverse perinatal outcome was neonatal asphyxia with encephalopathy, cardiovascular, respiratory, or renal complications. Now that the database is finalized, future plans include extensive data analysis and the preparation of papers. Depending upon the research findings, investigators will work with clinical entities to help identify possible guideline revisions.

Gestational Diabetes Mellitus (GDM)

BIOMARKERS

Excess adiposity is an important modifiable risk factor for the development of GDM. Mechanisms linking excess adiposity to the elevated risk of GDM are not completely understood, but recent evidence points to a crucial role for specific hormones and cytokines (called “adipokines”) secreted by the adipose tissue. A major breakthrough in understanding the link between adiposity and glucose intolerance has come from the demonstrated cross-talk between adipose tissue and other insulin-target tissues, such as skeletal muscle and the liver. Such cross-talk is mediated by a number of molecules that are secreted by adipocytes. Among those identified to date are adiponectin, resistin, retinol binding protein-4, leptin, and TNF- α . In concert, these adipokines are believed to adapt metabolic fluxes to the amount of stored energy, meaning that dysregulation of this network is a critical factor in the deterioration of insulin sensitivity. Despite the promising role of these adipocytes in glucose homeostasis, data on the longitudinal trend of these adipokines in pregnancy and prospective studies of them in association with GDM risk are sparse. The majority of available studies are small cross-sectional studies with blood specimens collected during late pregnancy.

For two ongoing Branch studies—the National Standard for Normal Fetal Growth Study (described later in this section) and the EAGeR Trial (described earlier in this section)—investigators are recruiting approximately 4,000 pregnant women and will longitudinally collect biospecimens. Biomolecular epidemiologic analysis will be conducted with these novel biomarkers of the adipogenesis pathways in relation to development of GDM and related pregnancy complications. Thus, this avenue of research will provide the platform of evidence on the pathogenesis of GDM using a systems biology approach.

MODIFYING RISK

GDM is one of the most common complications of pregnancy and is related to substantial short-term and long-term adverse health outcomes for both mothers and offspring. Moreover, maternal hyperglycemia during pregnancy impairs embryogenesis as early as the pre-implantation stages of development. Therefore, it is pivotal to identify modifiable risk factors among women at high risk to prevent the development of GDM and promote healthy pregnancy outcomes.

As explained earlier, Branch investigators and their collaborators at Harvard University analyzed data from the NHS to identify genome-wide signals of abdominal adiposity. These researchers also used NHS II data to identify dietary and lifestyle factors that increase the risk for GDM. By examining the joint effect of multiple modifiable factors, they made a number of important new findings. Specifically, they found that women with “healthier” lifestyles—defined as not being overweight or obese, habitually consuming a diet high in cereal fiber and low in glycemic load and sugar-sweetened beverages, engaging in moderate-to-vigorous physical activity for at least

30 minutes per day, and not smoking cigarettes—had a large reduction in risk for GDM compared with the remainder of the cohort. These findings suggest that a large proportion of GDM cases could be prevented by pre-gravid vigorous exercise, a prudent diet, and avoiding cigarette and excess weight. In light of these findings and those from other investigators, future intervention studies with populations at high risk for GDM are warranted. Researchers are also planning, within the preeclampsia study described below, a factorial study to evaluate the efficacy of diet and lifestyle interventions for improving maternal glucose homeostasis and relevant fetal, neonatal, and infant outcomes among pregnant women at high risk for GDM.

LIFE COURSE

A second novel avenue of GDM research focuses on a life-course approach to understanding its relation to the later onset of Type 2 diabetes. Although one-third of parous women with Type 2 diabetes reportedly have had a prior history of glucose intolerance during pregnancy, little research has focused on the genetic and/or environmental determinants of progression. To address this critical data gap, one Branch researcher has designed a retrospective cohort study to assess the progression of glucose intolerance in pregnancy to Type 2 diabetes and related metabolic disorders. With colleagues in the BBB, the researcher has developed a comprehensive statistical plan appropriate for longitudinal analysis of exposures, including the detection of gene-environment interactions and gene-gene interactions using established data-mining approaches, with added attention to measurement error and other potential bias (e.g., population stratification and multiple comparisons). This design will leverage resources by building upon existing cohorts of pregnant women who can be followed for in-depth prospective followup. Another aim of the proposed research is to create a biospecimen bank, which would allow for eventual deep sequencing of promising candidate genes to discover novel genetic loci for Type 2 diabetes.

Preeclampsia: Etiology and Prediction

The Calcium for Preeclampsia Prevention (CPEP) Trial, successfully completed in 1996, used banked biospecimens to allow extensive investigation on the role of angiogenic factors in the pathogenesis of preeclampsia and has revolutionized thinking about preeclampsia. Since the last report to Council, the investigators have completed three avenues of research using the banked CPEP biospecimens. These avenues are explained below.

ASSESSING CIRCULATING ANGIOGENIC FACTORS AND THE RISK OF PREECLAMPSIA

Branch investigators found that the hypertensive syndrome of preeclampsia could result from high concentrations of soluble fms-like tyrosine kinase-1 (sFlt-1) and soluble endoglin in maternal blood. sFlt-1, an anti-angiogenic protein, binds the pro-angiogenic proteins, vascular endothelial growth factor (VEGF), and placental growth factor (PlGF), thus preventing their interaction with endothelial cell receptors. Soluble endoglin is thought to prevent transforming growth factor beta (TGF β) from binding to the endoglin co-receptor. Blockades of VEGF and TGF β receptor signaling in endothelial cells induce endothelial dysfunction, which is the hallmark of preeclampsia.

Branch investigators conducted two nested case-control studies utilizing the resources of the CPEP Trial. In normotensive control women, concentrations of sFlt-1 and soluble endoglin increased, and the concentration of free PlGF decreased during the last two months of pregnancy.

These changes occurred earlier and were more pronounced for women in whom preeclampsia later developed. Free PIGF levels were also significantly lower in the women who later developed preeclampsia than in the women who remained normotensive during pregnancy, with the greatest difference occurring in the five weeks before the onset of preeclampsia, coincident with the increase in sFlt-1. Alterations in the levels of sFlt-1, soluble endoglin, and free PIGF were greater in women who had an earlier onset of preeclampsia, and in women for whom preeclampsia was associated with delivery of a small-for-gestational-age infant. Increased levels of sFlt-1 and soluble endoglin and reduced levels of PIGF predicted the subsequent development of preeclampsia. This finding, especially in concert with observations of reduced PIGF in urine during mid-pregnancy and in the weeks before the onset of preeclampsia, has led to the development of predictive tests for preeclampsia. A pharmaceutical company is now developing a treatment based upon these findings, and several companies have developed rapid, accurate diagnostic and predictive tests for clinical use.

ASSESSING URINARY PLACENTAL GROWTH FACTOR (PLGF) AND THE RISK OF PREECLAMPSIA

Branch investigators conducted a nested case-control study within the CPEP Trial to quantify the concentration of PIGF in urine specimens obtained before labor or delivery. In women who remained normotensive during pregnancy, concentrations of urinary PIGF increased during the first two trimesters, peaked at 29 to 32 weeks of gestation, and decreased thereafter. Among women who subsequently developed preeclampsia, the pattern of urinary PIGF was similar, but levels were significantly reduced beginning at 25 to 28 weeks' gestation. Decreased urinary PIGF at mid-gestation was strongly associated with subsequent early development of preeclampsia.

ASSESSING SOLUBLE FMS-LIKE TYROSINE KINASE-1 (SFLT-1) AND THYROID FUNCTION

Branch researchers conducted another nested case-control study to quantify thyroid-stimulating hormone (TSH) in blood obtained before 21 weeks of gestation (baseline) and after preeclampsia onset (pre-delivery). In pre-delivery samples, TSH concentrations increased much more in women who developed preeclampsia compared to baseline levels and compared to women who remained normotensive during pregnancy. Women with preeclampsia were more than twice as likely as controls to have concentrations of TSH above the reference range. The increase in TSH between baseline and pre-delivery specimens was strongly associated with levels of pre-delivery sFlt-1.

Subsequently, a collaborative effort with Norwegian investigators found that women with a history of preeclampsia were more likely than other women to have TSH concentrations above the clinical reference range. The association was particularly strong if preeclampsia had occurred both in the first and second pregnancies. Elevated serum concentration of sFlt-1 during preeclampsia was associated with subclinical hypothyroidism during pregnancy, suggesting that preeclampsia may also predispose women to reduced thyroid function in later years. This avenue of research supports a life-course epidemiologic approach to complex diseases in that gravid health may affect later adult diseases.

As followup to these exciting novel findings, Division researchers are working on a cohort study aimed at delineating the pathogenesis of preeclampsia in women with chronic hypertension or obesity. This research is expected to commence in fiscal year 2010.

National Standard of Normal Fetal Growth Study

Normal fetal growth is a critical component of a healthy pregnancy and of the long-term health of the child. Currently, there is no commonly accepted standard defining normal and abnormal fetal growth. Babies with a weight less than the 10th percentile are not necessarily growth restricted (e.g., constitutionally small but healthy babies), while babies above the 10th percentile are not necessarily of normal fetal growth. Thus, an objective assessment of normal and abnormal fetal growth has enormous utility in prenatal care, neonatal care, and outcome-based research.

Moreover, twin pregnancies have become increasingly common since 1980, due in part to the use of assisted reproductive technologies (ART). Twin gestations have substantially higher risks for perinatal and maternal morbidity and mortality. On average, relative to singletons, twins: are born with a lower mean birth weight, shorter gestation, and a higher rate of fetal growth restriction; are four times more likely to develop cerebral palsy; and have a seven-fold increased risk of infant mortality. Scientific understanding of twin fetal growth is limited in that only a few longitudinal studies of twin pregnancy have been conducted, most involving small sample sizes.

Branch investigators designed the National Standard of Normal Fetal Growth Study to address this critical data gap in contemporary obstetrical practice. The original research began in September 2008 through contracts with four clinical sites: Columbia University; Northwestern University; Medical University of South Carolina; and University of California, Irvine. The primary research aims are to:

- Establish a U.S. national standard for normal fetal growth (velocity) and size for gestational age;
- Create an individualized standard for optimal fetal growth; and
- Improve accuracy of fetal weight estimation.

Secondary objectives reflect follow-on studies that were possible through competitive funding from the NIH Office of Dietary Supplements (ODS) and additional Division contract resources. Follow-on studies include: an assessment of nutrition and dietary supplementation during pregnancy; collection of blood samples for a prospective study of GDM and for a prediction study of fetal growth restriction and/or overgrowth; and collection of placental tissues and umbilical cord blood for studies on the etiology of idiopathic fetal growth restriction.

The National Standard Study will recruit approximately 2,400 healthy low-risk women of mixed race/ethnicity—specifically, non-Hispanic white, African American, Hispanic, and Asian/Pacific Islander women (600 women in each group)—with an *in utero* singleton pregnancy at less than 13 weeks of gestation. Each woman will be assessed five times during pregnancy with 2-dimensional and 3-dimensional ultrasound scans. A comprehensive nutritional assessment during the pre- and peri-conception periods and throughout pregnancy is being conducted with partial funding from the ODS. After delivery, researchers will perform neonatal anthropometric measurements.

This project was subsequently selected as one of the NIH's Signature Projects and, thereby, received supplemental funding under the American Recovery and Reinvestment Act (ARRA) of 2009. ARRA funds will permit the recruitment of 500 twin pregnancies as well as the addition of four new clinical sites in fiscal year 2010. These funds will also allow researchers to administer dietary questionnaires to all the study participants (instead of to 25 percent of the subjects as originally planned), and to use ultrasound imaging to measure biomarkers for GDM, fetal growth, and organ development and components of fetal body composition.

Recruitment of study participants began on July 15, 2009, and is expected to last at least two calendar years. Upon completion of the study, data analysis will focus on five aspects: constructing nomograms for race/ethnic-specific fetal growth standards; modeling individualized standards for optimal fetal growth; assessing the consistency of results for high-risk subgroups, such as obese women or women with pregnancy complications, to validate the above standards; incorporating maternal characteristics with 2-D and 3-D ultrasound measurements to improve accuracy of fetal weight estimates; and constructing individualized standards for fundal height. Given the large amount of imaging data, Branch investigators will work closely with the BBB and will recruit a bioinformatics investigator to join the Division to appropriately handle the data.

PEDIATRIC EPIDEMIOLOGIC RESEARCH

Pediatric epidemiologic research focuses on the neonate, infant, or child as the unit of analysis, though dyad and triad designs are often incorporated, particularly for genetic-oriented etiologic research. The Branch currently has research in four focused areas, described below. These activities are also listed in [Table 5C](#).

Autism Spectrum Disorders (ASDs)

Children with ASDs suffer from defects in socialization, verbal and nonverbal communication, and response to sensory stimuli. There is evidence of accompanying gastrointestinal symptoms in some children. A high prevalence of macrocephaly and being taller than average are also associated with ASDs. Growth patterns, bone growth, and growth hormones in ASD children have not been studied in detail. With collaborators from Cincinnati Children's Hospital Medical Center, Branch investigators have studied 81 children, between ages four years and eight years, with ASDs and compared them to normal controls. Boys with ASD showed a progressive fall-off in appositional bone growth, measured by metacarpal cortical thickness, with the effect being significant at and after age six years. The fall-off was particularly pronounced when the boys were on dairy-free diets, that is, gluten- and/or casein-free diets, to moderate their autistic symptoms. Despite their slower bone growth, children with ASDs were found to be heavier than average, have increased head circumferences, and have significantly higher levels of several growth-related hormones, including insulin-like growth factor and growth hormone binding protein. Boys with ASD, ages six years to eight years, were also more likely to have measurable levels of dehydroepiandrosterone sulfate, a marker for adrenal maturation that is low in early childhood but increases during the mid-growth spurt.

These findings of increased growth hormones could help explain the significantly higher weights and head circumferences among boys with ASDs and suggest that these boys might have accelerated maturation, at least in the area of adrenal activation. However, from a clinical perspective, the most important observation in this study was the negative impact of gluten- and/or casein-free diets on bone development. Even though the efficacy of these elimination diets for improving symptoms of ASD has never been proven, many parents of children with ASDs want to include the diets as part of their children's therapy because of the multiple well-publicized, anecdotal testimonials devoted to the diets' benefits. In light of these research findings, nutrition experts are advising health care providers to discuss these elimination diets with parents of ASD children in the context of a risk-to-benefit ratio of decreased bone development and the potential for increased risk of fractures versus treating ASDs.

Birth Defects

ALCOHOL, LIFESTYLE, AND BIRTH DEFECTS

Intrauterine alcohol exposure and birth defects. Since 1995, researchers have followed a cohort of 100 women who reported heavy prenatal alcohol consumption (defined as four drinks per day on the average) and their offspring. They first documented the success of using home interviews to confirm heavy drinking; they have shown that children prenatally exposed to large amounts of alcohol have nerve-conduction problems; and they have shown that prenatally exposed children who did not develop fetal alcohol syndrome, a specific syndrome characterized by a pattern of poor growth, developmental problems, and abnormal facial features, were not at increased risk for eye malformations or vision problems when compared to unexposed infants. Only a few children of heavy drinking mothers (the approximately 10 percent who develop fetal alcohol syndrome) were at risk for eye problems.

Maternal periconceptional smoking, alcohol consumption, and risk for selected congenital anomalies. Numerous human studies have investigated the potential teratogenic effects of maternal smoking during pregnancy, and they have produced conflicting findings. Meanwhile, the adverse impact of peri-conceptional alcohol consumption on the growth and mental development of the fetus—collectively referred to as fetal alcohol syndrome—is well established. The association of alcohol consumption with major congenital anomalies, especially those not characteristic of fetal alcohol syndrome, remains a matter of debate. Using data from a large population-based case-control study in California, researchers assessed the association between the risks for NTDs, conotruncal heart defects, and orofacial clefts in offspring and patterns of maternal smoking and alcohol consumption, including binge drinking, during the peri-conceptional period. The main findings of the study, which included 1,698 cases and 907 controls, were that maternal alcohol intake during the peri-conceptional period increased the risk for conotruncal heart defects, NTDs, and multiple cleft lip with or without cleft palate in infants.

Socioeconomic characteristics and NTDs. The higher frequency of neural tube malformations (secondary to abnormal neural tube closure which occurs between the third week and fourth weeks of gestational age) among children born to women of lower socioeconomic status (SES) has been well documented in the epidemiological literature dating back to 1958. The SES measures in these previous studies, however, were generally limited to individual attributes and

did not consider the features of the neighborhoods where the study respondents resided. A Branch investigator used data from a large population-based case-control study (441 cases and 786 controls) in California to simultaneously investigate the role of individual and neighborhood socioeconomic characteristics as risk factors for NTDs. This study determined that low maternal education—especially among those women who lived in less educated neighborhoods—was associated with an elevated risk of an NTD-affected pregnancy.

Paternal age and birth defects. Although numerous studies have investigated the role of maternal age in the genesis of congenital anomalies, relatively less research has been devoted to the relationship between paternal age and the risk of birth defects. The existing studies are generally limited by small samples and a focus on narrow sets of defects. Again using data from an active surveillance program in California, Branch researchers examined the association between paternal age and a wide range of birth defects. This study demonstrated that, after adjustment for maternal age, both older and younger paternal age was associated with select birth defects in California between 1989 and 2002. Specifically, older paternal age was associated with a 10-percent to 33-percent higher risk of anomalies of the nervous system, the upper and lower limbs, and the integument. Meanwhile, younger paternal age was associated with a 7-percent to 13-percent higher risk of amniotic bands, pyloric stenosis, and anomalies of the great veins.

GENETIC DETERMINANTS OF BIRTH DEFECTS

NICHD-Health Research Board of Ireland Study. This longstanding collaboration, initiated in 1992, recently identified two new genetic risk factors for NTDs. The first new risk variant is in the gene that codes for the vitamin B₁₂ (transcobalamin 2) transporter receptor; the second is in the tumor protein p53. The data showed both maternal and case associations with the second variant.

This large dataset also has the power to confirm or refute associations reported by other studies. For instance, investigators reported negative results among the Irish population for a number of SNPs previously reported as NTD risk factors. As researchers analyze data from this large dataset of NTD cases—mothers, fathers, and controls in which 1,536 SNPs were genotyped from a custom panel of candidate genes—preliminary analysis indicates that several genes may be related to NTDs.

Investigators also confirmed the maternal risk factor, MTHFD1, in various birth defects. In their studies of potential genetic risk factors for oral facial clefts, the researchers reported that the well-known variant MTHFR 677TT and MTHFD1 variant R563Q were significantly more common in mothers of children with isolated cleft palate than in mothers of unaffected children. The researchers recently expanded the clefts investigation to look at genes reportedly associated with clefts in previous studies.

Biochemical factors as risk factors for NTDs also continue to interest researchers. Investigators recently confirmed that vitamin B₁₂ is an independent (from folate) risk factor for NTDs in the Irish population. More importantly, investigators showed—for the first time—that women with deficient or borderline levels of vitamin B₁₂ were at substantially higher (two to three times) risk

for having an affected child than women whose serum B₁₂ levels were within the normal range. Investigators also found that the presence of folate-receptor antibodies was not significantly associated with an NTD-affected pregnancy.

In another component of the NICHD-Irish collaboration, investigators are assessing existing dietary and lifestyle information as well as genotyping and conducting a wide range of biological assays on a sample of 2,524 university students in Dublin. The objective of this effort is to identify genetic variants that influence levels of biologically important chemicals, such as vitamins. Preliminary analysis using the questionnaire data and vitamin level samples indicates that alcohol consumption in this young population is already causing adverse effects; that is, students who were the heaviest drinkers were more likely to show at least one abnormal level of liver function and lower levels of B vitamins than lower consumers. Researchers are currently implementing a GWAS investigation with the goal of relating genetic variants to high and low levels of key analytes, such as vitamins, to identify genetic risk factors for nutritional problems.

Birth defects-genes study. Investigators are currently collaborating with the New York State Department of Health (NYS DOH) and the National Human Genome Research Institute to look for genetic risk factors for birth defects. By extracting and amplifying DNA from banked newborn blood spots maintained by the NYS DOH, the researchers are examining 24,000 children born with birth defects (2 percent of live births) between 1998 and 2005, as identified by the New York State Congenital Malformations Registry. To date, the researchers have sent samples for 486 infants with omphalocele and Hirschsprung's disease and 1,973 samples from unaffected infants for genotyping and sequencing to test SNPs from candidate genes.

In the next phase of the study, investigators will identify and genotype infants with pyloric stenosis, limb defects, diaphragmatic hernias, fetal alcohol syndrome and other alcohol-related anomalies, and anorectal atresia. Investigators will examine the genotyping results for associations between variants and the birth defects of interest.

Drowning: Etiology and Prevention

Unintentional injuries are the single leading cause of death among children, and drowning is the second leading cause of death from unintentional injury in the United States. During the past four years, Branch investigators concluded their investigations on the epidemiology of childhood drowning with the goal of providing information on which to base more effective prevention strategies. Specifically, EB investigators, along with investigators from the PRB, conducted a case-control study of childhood drowning. Participating medical examiners' offices in 18 jurisdictions (142 counties) across the United States identified drowning victims, and random-digit dialing identified appropriately matched controls. The researchers conducted structured interviews with families of case and control children to identify risk and protective factors for childhood drowning.

Results of this study demonstrated that only two of the 61 preschool-aged children who drowned had participated in formal swimming lessons. The corresponding percentage for age-sex-neighborhood matched control children was 26 percent, yielding an adjusted odds ratio of 0.12 (95% CI = 0.12 to 0.97). If this association were causal, it suggests that participation in formal swimming lessons reduces the risk of drowning in children ages one year to four years by

88 percent. This study was accompanied by an editorial calling for all children to receive swimming lessons. The data were also considered by the AAP in revising its policy for the prevention of drowning (revised policy is currently embargoed). Final analyses and publications for this study are in progress.

Growth and Development

UPSTATE NEW YORK INFANT DEVELOPMENT SCREENING (KIDS) STUDY

A growing body of scientific evidence suggests that infertility treatment may impact human health and development, placing resulting children at risk for developmental disabilities or growth disorders. The few U.S. follow-up studies conducted to date relied on clinic-based rather than population-based samples, had high attrition—particularly for affected children—and/or had inadequate followup for addressing issues of catch-up growth or development.

To address these critical data gaps, in 2008 Branch investigators designed and implemented a population-based matched-exposure cohort study to:

- Determine if infertility treatments, such as ovulation-stimulating medications and other ART, are associated with deficits in the growth, motor, and/or social development of children from birth through age three years.
- Test and refine the AAP's developmental surveillance and screening algorithm, using parent-report developmental screening tools, to augment routine pediatric care and to develop models for identifying infants and children in need of developmental assessment, diagnosis, and early intervention.

Using data from the New York State (exclusive of New York City) Perinatal Data System, the Upstate KIDS Study is recruiting approximately 1,500 families whose child(ren) were conceived with infertility treatments as listed on birth certificates (exposed cohort) and 4,500 regionally matched families whose child(ren) were not conceived by infertility treatment (unexposed cohort). Developmental screening by parent report is conducted at 4, 8, 12, 18, 24, 30, and 36 months of chronologic or gestation-corrected age, and screening for ASDs is conducted at ages 18 months and 24 months. Children who do not pass are referred into the New York State Early Intervention Program and tracked through that system. Participating mothers complete the five-item short-matrix version of the self-rating Edinburgh Postnatal Depression Scale to screen for postpartum depression at baseline and then yearly. All affected women are referred to local county mental health services. To date, approximately one-third of the families from the exposed and 1,302 families from the unexposed cohorts have been recruited.

To validate reported ART treatment, the cohort will be linked with the Society for Assisted Reproductive Technology cycle-based database during the coming year. Branch researchers are using residual newborn blood spots to quantify possible environmental confounders (e.g., PCBs) of growth and development. Lastly, investigators are finalizing plans for the inclusion of a standardized assessment for diagnosing developmental disabilities using a battery of empirically validated and reliable instruments at 24 months to 30 months of age for all children who fail the neurodevelopmental screens.

PUBERTY: ENVIRONMENTAL INFLUENCES

Data on the patterns of pubertal onset, that is, in children as young as six years to eight years of age, and on how and whether environmental toxicants may be implicated in the decline or contribute to a delay in pubertal onset are scarce and have generally been confined to cohorts of older children and adolescents. To address this important issue, researchers are utilizing stored biospecimens (serum) for children who were examined as part of the Third National Health and Nutrition Examination Survey (NHANES III) between 1988 and 1994. Objectives of this effort are to: estimate, by assay of hormones (luteinizing hormone and inhibin B for boys and girls, testosterone for boys), the timing of the onset of pubertal development in children, ages six years to 11 years, and the concordance based on physical maturation (Tanner sexual maturation scores) at ages eight years to 11 years; and determine if the recent findings linking blood lead (Pb) levels and delayed maturation, based on Tanner scores and age at menarche in girls, can be confirmed by hormonal analysis and extended to younger ages, and whether there is an effect at all for young boys. The NHANES III data are already available, and the researchers newly assayed hormones in 2008 using residual specimens.

In collaboration with investigators at the Milton S. Hershey Medical Center, in Hershey, Penn., and at the University of Minnesota, Branch researchers documented the distribution of testosterone and inhibin B in 228 non-Hispanic white, 266 non-Hispanic black, and 288 Mexican American boys. Both hormones increased with age, and testosterone increased with each Tanner pubic hair stage (1, 2, 3+), although testosterone concentrations did not distinguish most boys assigned Tanner genital stage 2+. Inhibin B was significantly associated with genital stage, adjusting for age and race/ethnicity. Interestingly, levels of inhibin B were significantly higher for non-Hispanic black boys, particularly among those who were prepubertal. Further assessment is needed to verify these racial/ethnic differences, and to determine if these differences are related to mean age of puberty onset and possibly greater testicular volume (the main source of inhibin B is the Sertoli cells in the testes). These findings are currently under review.

Researchers also evaluated the relation between lead (Pb) levels and hormonal maturation in 667 girls, ages six years to eleven years. Blood Pb was inversely and significantly associated with inhibin B. Girls with higher Pb levels ($\geq 5 \mu\text{g/dL}$) were 80 percent less likely to have inhibin B values which exceeded the cut-off indicating the onset of puberty, when compared with girls whose Pb values were lower ($<1 \mu\text{g/dL}$). The investigators also found a significant interaction between blood Pb and urinary cadmium in decreasing inhibin B—a finding which implies that the onset of puberty may be delayed in girls with Pb exposure even within non-toxic levels, a joint effect of high Pb and cadmium on sexual hormone concentrations, and an endocrine mechanism for later maturation in exposed girls. These results are in contrast to findings on 767 boys for whom Pb levels were not associated with inhibin B, but instead showed a significant positive association between Pb and testosterone, even at low blood Pb levels. The results for boys are consistent with studies in men that showed low-level Pb exposure was associated with increases in testosterone. These findings are also under review.

Methodologic Research

The EB also conducts methodological research on a number of topics. Some of these efforts, also listed in [Table 5D](#), include the following:

- **Causal Inference: The Birth Weight Paradox.** Low birth weight infants born to women who smoked have a lower mortality rate than infants born to non-smoking mothers, a situation which leads to the so-called “birth weight paradox.” Branch investigators have taken multiple approaches to evaluate this issue and to facilitate researchers’ understanding of the statistical modeling factors that contribute to the paradox. These efforts also incorporate design strategies suitable to use in novel statistical methods for assessing causality, particularly the use of directed acyclic graphs (DAGs), to graphically evaluate bias, confounding; and to possibly explain the paradox. Branch investigators demonstrated that the long-debated paradox is a statistical artifact and is not a biologically meaningful finding. This research has implications for other alleged exposures which may arise from the same statistical source.
- **Modeling Mixtures for Human Health Effects.** There is a great deal of interest in how best to model mixtures reflecting human biology (e.g., a panel of cytokine biomarkers) or environmental exposure (e.g., chemical mixtures). However, there are few statistical methods for analyzing mixtures relative to human health, especially when sample sizes are low (comparable to the small “n” big “p” problem in micro-array studies). Such mixtures can lead to colinearity or highly correlated data structures, which require appropriate modeling assumptions for analysis. Branch investigators have utilized DAGs to define the research questions and quantify the effects of colinearity on causal research.
- **Pooling Designs for Biomarkers.**
 - o Many epidemiologic and clinical studies include biomarkers, which add cost, particularly for emerging molecules. In an effort to minimize laboratory cost while maximizing biospecimens, investigators have developed methods for pooling biospecimens as well as a hybrid pooled and unpooled study design. Pooling designs allows investigators to group study participants by disease status and other pertinent covariates, thereby, maximizing the amount of biological information assessed while holding constant the number of assays conducted. This increased efficiency of estimation is achieved while fixing costs, resulting in a highly useful study design. Moreover, pooling specimens minimizes issues with laboratory limits of detection.
 - o Other methodologic issues pertaining to the quantification of biomarkers include: research to empirically demonstrate that the automatic substitution of values below laboratory limits of detection may introduce bias when assessing health outcomes, and that ROC curves can be used to evaluate biomarkers. Additionally, adequate exposure assessment necessitates consideration of measurement error, which may arise from laboratory equipment, variation between technicians, temporal changes, and biological variability. Branch investigators continue to evaluate biases associated with laboratory processes and their impacts on estimating health risks.

PREVENTION RESEARCH BRANCH (PRB)

MISSION AND SCOPE

The mission of the PRB is to conceptualize, design, and conduct research, mentor young researchers, and provide professional service. PRB research is designed to identify determinants of child and adolescent health behavior, and to test the efficacy and effectiveness of educational, behavioral, and environmental strategies for improving or protecting child and adolescent health. The PRB currently has three primary programs of research: young drivers, including prevention of motor vehicle crashes; adolescent health behavior; and family management of childhood disease. These programs and their activities are described later in this section.

The Branch's research is guided by a concern for the public health importance of its work, the state of the science, and the expertise and interests of the research staff. This work includes both observational and intervention studies and is grounded in theory and research on child and adolescent development and on parenting. Moreover, much of the Branch's research is translational. For example, basic research identifies risk factors for motor vehicle crashes among novice teenage drivers; these findings can then guide national licensing policies. In the tradition of intramural research at the NIH, PRB staff also train emerging researchers, provide scientific and professional consultations, and advise the Division, the NICHD, and the NIH on relevant topics.

RESEARCH MISSION

As mentioned, the PRB has three productive programs of research, each involving topics that are of significant public health and clinical relevance. This work involves multiple investigators and staff, consists of multiple studies, and includes both observational and intervention studies. Within each program, the studies are phased—that is, some are finishing, while some are in progress, and while others are in development. This type of scheduling makes optimal use of limited staff and allows scientific findings to be incorporated into subsequent studies.

The PRB now has two major contracts in the area of young driver research—one supporting several observational studies, and one supporting several evaluations of the Checkpoints Program. The latter includes a comparative effectiveness study and two translational studies to evaluate the adoption, dissemination, and cost effectiveness of the Checkpoints Program statewide in Michigan. A contract is in place for fiscal years 2009-2010 to complete the Health Behavior in School Children (HBSC) cross-sectional survey, while also establishing the NEXT longitudinal cohort study. These efforts also receive extramural funding from the NICHD, the Health Services Research Administration (HRSA), the National Heart, Lung, and Blood Institute (NHLBI), and the National Institute of Alcohol Abuse and Alcoholism (NIAAA). The Family Management of Childhood Diabetes (FMOD) Study, the Branch's first multisite randomized trial, is the largest and most expensive study in the history of the PRB. FMOD, which evaluated the effectiveness of a clinic-linked behavioral intervention on diabetes outcomes, is in the data analysis stage. A new study, Enhancing Carbohydrate Quality, is a single-site randomized

intervention trial testing the effects on diabetes outcomes of a family-based, clinic-linked behavioral nutrition intervention.

[Table 6](#) provides a brief overview of the investigator-initiated research projects within the Branch's portfolio. The Branch's staff are listed in [Appendix A](#), and its fellows and interns are listed in [Appendix B](#). PRB staff publications are listed in [Appendix C](#), and staff professional service, awards, and symposia/presentations are listed in [Appendix D](#), [Appendix E](#), and [Appendix F](#), respectively.

RESEARCH ON YOUNG DRIVERS

Motor vehicle crashes are the leading cause of death among children and adolescents. To address this issue, the PRB has established one of the world's premiere research programs on novice young drivers. Using naturalistic and experimental methods, the PRB research seeks to determine:

- The nature of motor vehicle crashes and the subgroups most at risk;
- How driving improves over time;
- The driving conditions and behaviors associated with crashes;
- Effects of social influences on driving performance; and
- Solutions to novice young driver problems.

Branch research in this area includes the first naturalistic study of novice teen drivers that involves equipping the vehicles of 40 newly licensed teenagers with cameras and accelerometers to advance investigators' understanding of novice teenagers driving performance and risk. Experimental research underway also seeks to determine how teen passengers affect simulated driving. Other research aims to determine the utility of event monitors installed in the vehicles of novice teenage drivers; these monitors provide real-time feedback to the driver and weekly reports to parents on risky driving (defined as elevated g-force events), such as rapid stops and sharp turns. The Branch is also involved in a series of randomized trials to investigate the effectiveness of the Checkpoints Program on parental management of novice teen drivers. This research is translational in that the adoption and diffusion of the Checkpoints Program is now being evaluated in several ongoing studies. A Web site is in development that will make the Checkpoints Program available at no cost to public organizations, which agree to implement the program as designed.

[Table 6](#) lists the studies focusing on young drivers. [Table 6A](#) includes observational and experimental studies of teenage driving performance. [Table 6B](#) includes randomized trials evaluating the effects of the Checkpoints Program. Details about findings from this research are included below.

Young Driver Observational Studies

Building on findings from its earlier studies, the Branch has developed a series of observational studies to more fully evaluate the specific nature of teen driving risks.

STUDY 1: THE OBSERVED EFFECT OF TEEN PASSENGERS ON TEEN DRIVING PERFORMANCE

In this study, investigators first observed vehicles exiting high school parking lots. Then, they compared the speed and close-following performance of vehicles with teen drivers and passengers with usual traffic drivers. The teenage drivers drove faster and closer to the lead vehicle than did usual traffic drivers, particularly in the presence of a male teenage passenger. In contrast, female teenage passengers reduced risk for speed and close following among male teenage drivers.

STUDY 2: TEST TRACT ASSESSMENT OF TEEN DRIVING PERFORMANCE

This research involves several studies, conducted on a test tract, comparing novice teen driving performance at licensure and after six months or 12 months of licensure, and then comparing their performance to that of experienced adults. The research documented that novice teenage drivers at licensure and after six months of independent driving experience were less able to manage lighted intersections when engaging in a secondary task (such as using a cell phone) compared to experienced adults.

STUDY 3: THE NATURALISTIC (40-TEEN) DRIVING STUDY

This study is the first to use instrumented vehicles to evaluate driving performance. Other research showed that crash rates are extremely high immediately after licensure, but decline rapidly thereafter, consistent with learning effects. In this effort, researchers recruited 40 newly licensed teenage drivers instrumented the drivers' vehicles with cameras, motion sensors, Global Positioning System (GPS), lane trackers, and other equipment to enable the assessment of driving performance and events during the first 18 months of driving. The instrumentation produces complex imaging data that is best analyzed using bioinformatics methods (a recent emphasis of colleagues in the BBB). This research showed that crashes/near crashes and elevated g-force events (such as rapid stops and turns) were many times higher among teenage drivers compared to their parents. Elevated g-force events are also much higher among teenagers when driving alone or with teenagers in the vehicle compared to when with a parent in the vehicle. Risky driving and crash/near crash involvement remained high for teenage drivers compared to parents whose risky driving and crash/near crash experience was generally low and constant during the study period.

STUDY 4: THE EFFECTS OF PARENT-SUPERVISED PRACTICE DRIVING ON THE INDEPENDENT DRIVING PERFORMANCE OF YOUNG DRIVERS

Because there is no evidence that the nature or amount of parent-supervised practice driving effects independent driving performance, the Branch is conducting a naturalistic study, instrumenting the vehicles of 90 families with GPS, accelerometers, cameras, and other equipment during the learner's permit period and the first six months of independent driving. This study will provide the best available data on the nature of parent-supervised practice driving and will allow investigators to evaluate the effects of the amount of pre-licensed driving on independent driving performance.

STUDY 5: THE USE AND UTILITY OF ELECTRONIC MONITORING DEVICES ON NOVICE YOUNG DRIVER BEHAVIOR

This study examines the willingness of families of newly licensed teenage drivers to use electronic devices, specifically DriveCam technology, and evaluates actual utilization among families that agree to use it. The DriveCam records video footage within three seconds of each 0.5 g-force event (e.g., rapid stops, swerves, and contact with outside objects). Families are randomized to one of four feedback conditions. The study will provide information about the practical utility of this technology and will help explain the effects of different levels of feedback regarding driving performance.

STUDY 6: THE EFFECT OF AGE AND SEX OF PASSENGERS ON FATAL ACCIDENT RISK FOR DRIVERS IN VARIOUS AGE GROUPS

This study uses data from the Fatal Accident Reporting System and the National Household Travel Survey to evaluate the effects of various characteristics of teenage passengers on teenage driving performance. The study aims to provide better estimates of risk by imputing data on non-household passengers. Initial results indicated that teenage passengers, particularly male teenage passengers, increased fatal crash risk among teenage drivers, particularly among male teenage drivers, but also among adult male drivers.

STUDY 7: THE EFFECT OF TEEN PASSENGERS ON SIMULATED DRIVING PERFORMANCE

This study uses an experimental design to evaluate the effects of teen passengers on teen driving in a simulator. Male teenage drivers will be randomized to one of two passenger conditions: risk-accepting male passengers, or risk-adverse male passengers. The passengers are paid confederates, unknown to the study participants. The study is in progress.

Young Driver Intervention Studies

The Checkpoints Program is designed to motivate parents to manage novice teen driving. The program includes persuasive materials, including a nine-minute video titled, *Who Wants To Be a Driver?*, and other materials designed to increase perceived risk, outcome expectations, and self-efficacy for parental management by promoting the adoption of a parent-teen driving agreement. Branch researchers completed three randomized controlled trials evaluating the efficacy and effectiveness of the Checkpoints Program. Five additional trials currently underway are listed in [Table 6B](#). The studies currently in place are translational research projects designed to evaluate intervention timing, comparable effectiveness, cost effectiveness, Web applications, and state-wide adoption and dissemination of the Program.

STUDY 1: THE YOUNG DRIVER INTERVENTION STUDY

This study evaluated the effects of the Checkpoints Program on parental limits placed on novice teen drivers. More than 2,000 families were recruited at the time the teen obtained a learner's permit and were randomized to two treatment conditions. Families in the Checkpoints arm received persuasive communications designed to increase adoption of the Checkpoints Parent-Teen Driving Agreement and limits on high-risk driving conditions during the first year of licensure. The study demonstrated the Program's effectiveness, with treatment group differences favoring the Checkpoints Program for parental limits on high-risk driving, risky driving behavior, and traffic violations.

The information in this document is no longer current. It is intended for reference only.

STUDY 2: EFFECTIVENESS OF CHECKPOINTS PROGRAM AT PERMIT OR LICENSURE

This study is designed to evaluate the relative effectiveness of the Checkpoints Program when administered at permit, licensure, or both. Researchers are currently conducting their analyses of the data.

STUDY 3: THE MICHIGAN DRIVER EDUCATION STUDY 1

This study is a group-randomized trial designed to evaluate the effects of the Checkpoints Program when administered within driver education classes. At follow-up, families in the Checkpoints Program condition were two times more likely to adopt a parent-teen driving agreement.

STUDY 4: THE MICHIGAN DRIVER EDUCATION STUDY 2

The Centers for Disease Control and Prevention funded a follow-on study of the Michigan Driver Education Study 1 to evaluate the effects of the Checkpoints Program when administered by trained driver education instructors and not by professional staff. The study will examine the translation of the Checkpoints Program into Michigan driver education practice and the efficacy of Program delivery by driving school instructors.

STUDY 5: THE CONNECTICUT YOUNG DRIVER SOCIAL NETWORK STUDY

This study is designed to evaluate the effects of an online social network intervention in addition to driver education administration of the Checkpoints Program. This research evaluates the translation of the Checkpoints Program into the State of Connecticut's new Graduated Driver Licensing Program, which requires parents to attend one driver education class.

STUDY 6: CHECKPOINTS AND AMERICAN AUTOMOBILE ASSOCIATION (AAA) WEB-BASED PROGRAM

AAA is also supporting research on the efficacy of a Web-based version of the Checkpoints Program. A formal agreement between the NIH and AAA was negotiated to protect the Checkpoints Program trademark and the NIH's intellectual property and data rights. This research will evaluate AAA's translation of the Checkpoints Program into practice.

RESEARCH ON ADOLESCENT BEHAVIOR

Substance use, aggression and violence, diet, and physical activity are among the nation's most pressing adolescent health concerns. The prevention of these problem behaviors depends on a firm understanding of the factors associated with their prevalence. PRB research in this area is listed in [Table 6C](#) and is described below.

Study 1: The 2005 Health Behavior in School Children (HBSC) Survey

This national survey is part of the larger HBSC Survey, conducted in the United States and 41 other countries every four years to assess the prevalence of and trends in behaviors and associated social factors. The Surveys' aim is to assess the prevalence of adolescent health behaviors and to identify contextual factors associated with them in a national probability sample of sixth-grade to tenth-grade students. The study includes a survey completed by students and a questionnaire completed by school administrators; combined, these instruments provide more complete information regarding the school context for health behaviors. The 2005/2006 U.S.

HBSC Survey yielded a large number of papers on prevalence and associations with diet, physical activity, substance use, and bullying; in fact, the HBSC is among the first national studies to examine cyber-bullying in the United States. The findings on bullying and cyber-bullying suggest significant roles for parents and peers; the findings are affecting school policy and programs on this topic. Additional findings demonstrated the extent of the obesity epidemic by comparing rates in U.S. adolescents to rates in other HBSC countries. Analyses also indicated the potential negative effects of sedentary behavior on a range of physical, social, and psychological health indicators.

Study 2: 2009 HBSC

The design of the 2009 HBSC will enable PRB researchers to examine eight-year trends in U.S. adolescent health behaviors and health status. This effort will explore cross-national comparisons related to obesity, substance use, bullying, and physical and psychosocial health status.

Study 3: NEXT Generation Longitudinal Health Study

This longitudinal study, the only prospective cohort study involving a nationally representative sample of older adolescents, will follow a sample of tenth graders for four years into the year after high school. The goals of the NEXT Generation Study are to:

- Identify the trajectory of adolescent health status and health behaviors from mid-adolescence through the post high-school year;
- Examine individual predictors of the onset of key adolescent risk behaviors and risk indicators during this period;
- Identify family, school, and social/environmental factors that promote or sustain positive health behaviors; and
- Identify transition points in health risk and risk behaviors and changes in family, school, and social/environmental precursors to these transitions.

In addition to contract support from the NICHD, the study is supported by interagency agreements with HRSA, NHLBI, and NIAAA.

RESEARCH ON MANAGEMENT OF CHILDHOOD DISEASE

The Branch's work in this area focuses on diabetes, one of the most prevalent childhood diseases, which, when poorly managed, can have devastating consequences on health and longevity (see [Table 6D](#)). Despite advances in medical treatment, management is complicated: children and adolescents, assisted by their parents, must check their blood glucose levels multiple times daily and dose accordingly with insulin via injection or a continuous pump. In addition, diet, physical activity, sleep, stress, and other factors impact levels of hemoglobin A1c (HbA1c), a reliable measure of disease control. Failure to maintain good insulin control can lead to acute events (e.g., ketoacidosis) and long-term health consequences (e.g., blindness, kidney failure, neuropathies). Unfortunately, adherence to medical advice is far from perfect and falters during adolescence, particularly with regard to communication between parents and children and

poor problem solving and execution of complex management tasks on the part of the affected child or adolescent. Hence, there is a great need to develop methods to improve adherence and self-management, particularly during the challenging period of transition from pre-adolescence through adolescence. Branch research in this area is designed to better understand the nature of adherence problems and to test practical clinic-linked and home-based interventions.

The Branch recently developed a program of research focusing on family management of diabetes during childhood and adolescence, including how best to transition oversight from parent(s) to child. This research program encompasses two primary areas of inquiry. The first area—management of the diabetes regimen—examines parent, child, and family factors in relation to disease management and addresses the efficacy of behavioral approaches for improving behavioral and physiological outcomes. The second area of research addresses dietary management in diabetes, including the relationship of parent and child factors to dietary intake, the relationship of dietary intake to diabetes-related outcomes, and the efficacy of behavioral intervention in promoting healthful dietary behaviors. These areas are described in more detail below.

Management of the Diabetes Regimen

STUDY 1: FAMILY MANAGEMENT OF CHILDHOOD DIABETES (FMOD)

This multisite intervention study, conducted at four clinical sites in Massachusetts, Florida, Illinois, and Texas, tests the efficacy of a clinic-integrated family-based behavioral intervention designed to facilitate adherence among youth with Type 1 diabetes during the management transition that occurs during late childhood and early adolescence. The intervention, which is delivered in low intensity over time, is designed to promote problem-solving skills and to address child, parent, and dyadic factors, which may impact management practices. Branch researchers followed families participating in the study for two years, during which time those in the intervention condition participated in a family problem-solving process applied to a family-selected adherence issue during each routine clinic visit (approximately every three to four months).

An abbreviated pilot study to assess feasibility of the study approach preceded the full trial. Findings from the pilot study supported the feasibility of the intervention approach and the study methods. The pilot study also yielded several novel publications addressing measurement issues and family behaviors predictive of diabetes management. Analysis of the data from the main trial is underway.

STUDY 2: DEVELOPMENTAL INFLUENCES ON DIABETES MANAGEMENT

This observational study examined the influence of family, social, and behavioral variables on diabetes self-management, with a particular focus on adolescent developmental transitions. The study integrated assessment of both youth and parent variables to better understand the potential interactive and dynamic natures of factors predicting adherence. Investigators collected clinical (e.g., medical chart abstraction and HbA1c from finger stick) and self-report data at four time points during a two-year period. Resulting papers focus on measurement issues and psychosocial predictors of successful diabetes management.

STUDY 3: DIABETES PERSONAL TRAINER STUDY

This intervention study was designed to test the efficacy of an individualized, problem-solving intervention delivered by specially trained lay staff, such as nurses. Guided by principles of motivational interviewing and applied behavior analysis, the trainers met with youth for six structured sessions, during an approximately two-month period, to improve one or more youth-selected areas of diabetes management. Investigators then followed youth for two years post-intervention. Recent publications have documented the short- and long-term success of this intervention in improving glycemic control.

STUDY 4: TRANSITION FROM PEDIATRIC TO ADULT DIABETES CARE

The transition from pediatric to adult diabetes care is frequently accompanied by a failure to schedule or attend regular clinic appointments, problems with diabetes self-management, and a decrease in glycemic control. The purpose of this set of observational and intervention studies is to examine diabetes self-management and psychosocial concomitants before, during, and after the transition to adult care. Data analyses will begin in 2010.

Dietary Management in Diabetes

STUDY 1: ENHANCING CARBOHYDRATE QUALITY IN DIABETES MANAGEMENT

This randomized, controlled intervention study will test a behavioral intervention designed to promote consumption of lower glycemic carbohydrates from nutrient-dense whole foods. The project also aims to determine the efficacy of such a dietary change in promoting improved glycemic control and health outcomes among children and adolescents with Type 1 diabetes. The intervention, *Cultivating Healthy Eating in Families (CHEF)*, integrates principals of motivational interviewing, active learning, and problem solving with the use of intermittent continuous glucose monitoring to inform and reinforce dietary choices. Researchers will follow youth for 18 months to determine the impact of the intervention on dietary intake and subsequent diabetes-related and general health outcomes. Study recruitment is expected to begin early next year.

STUDY 2: DIETARY INTAKE IN PEDIATRIC TYPE 1 DIABETES

This cross-sectional study examines the influence of social and cognitive factors on dietary intake among children with Type 1 diabetes, as well as the relationship between dietary behavior and diabetes management. Investigators measured both child and parent dietary intake and social cognitive factors to facilitate an understanding of dietary behavior in the family context. In addition, a series of focus groups were conducted with both parents and children (separately) to provide in-depth information regarding perceptions about healthful eating, the intersection of healthful eating with diabetes management, and relevant barriers and facilitators. Analyses of data, now in progress, guided main trial procedures, including assessment and intervention development.

STUDY 3: BLOOD GLUCOSE RESPONSE TO MEALS OF VARYING GLYCEMIC INDEX IN YOUTH WITH TYPE 1 AND TYPE 2 DIABETES

This pilot study tested blood glucose response to low and high glycemic-index meals using continuous glucose monitoring. Youth with Type 1 diabetes, Type 2 diabetes, or impaired glucose tolerance participated in five days of continuous glucose monitoring, during which they received both low and high glycemic-index meals in a structured clinic setting and *ad libitum* in

the home environment. Primary outcomes were daytime and nighttime mean blood glucose levels and blood glucose variability. Findings indicated the significant and clinically relevant beneficial effect of a low glycemic-index diet for improving blood glucose levels and for reducing blood glucose variability. The findings also indicated the potential utility of continuous glucose monitoring for assessment and of behavioral feedback for use in the larger trial.

STUDY 4: FEASIBILITY AND ACCEPTABILITY OF A LOW GLYCEMIC-INDEX DIET IN THE DIABETES CAMP SETTING

This pilot study was designed to address issues of feasibility and acceptability in dietary change among youth with Type 1 diabetes. Youth attending a diabetes summer camp received standard diabetes camp menus and lower glycemic-index diabetes camp menus on alternating days. Youth ratings of satisfaction and observations of consumption served as primary outcomes; feasibility of institutional preparation and cost were also examined. Findings supported the feasibility of the targeted dietary change.

BOARD OF SCIENTIFIC COUNSELORS (BSC) REVIEW, PROGRESS, AND FUTURE DIRECTIONS FOR THE DIVISION

Like other NICHD components, the Division undergoes a combination of internal planning and review as well as external review to determine its possible future research directions. Branches hold annual retreats to discuss research progress from the previous year, review the status of projects, and consider extending and adding to research topics. In addition, the BSC, a panel of external scientists who have expertise on topics related to the Division, also reviews the Division portfolio every four years. The most recent Board review was held in 2008. Using the results from these retreats and reviews along with emerging public health concerns, the Division leadership plans its possible future research directions.

The remainder of this section summarizes the BSC review for the Division as a whole and for its Branches, highlights progress toward achieving Division and Branch goals, and outlines possible future research directions.

BSC REVIEW

The BSC noted the success of the Division as measured by the productivity of its researchers, the volume and quality of the publications, and the visibility and reputation of the investigators and of the work done in the Division. The BSC recommended several possible directions for the Division's future course, including efforts to develop an overarching vision for the Division's research program that promotes collaboration across Branches, centralizes funding decisions, and eliminates administrative obstacles for planning and implementing research. Some of the obstacles noted were an unpredictable budget, insufficient research and administrative staff, and the need for a permanent Division director and chief of the BBB.

BSC Review of the BBB

The BSC noted the talent and abilities of the BBB, but added that the Branch's efforts have been hampered by the absence of a Branch chief. The BSC applauded the Branch's strong research record, but also noted concern that BBB research was not properly aligned with the mission of the Division. With the appointment of the new Branch chief, the BBB can focus on a revitalization, an effort strongly encouraged by the BSC, including recruitment of additional tenure-track positions.

BSC Review of the EB

The BSC noted that the EB is a major resource for the NICHD both in terms of the Branch's breadth of expertise and of the productivity and respectability of its investigators. BSC members added that the investigators reflect well on both the Division's mission and scientific reputation. Suggestions from the BSC for future activities for the EB included finalizing a strategic plan, increasing communication within the Branch and with other Branches, increasing collaborations with other intramural epidemiologic programs, and making efforts to rectify infrastructure barriers.

BSC Review of the PRB

The BSC reviewers identified a number of the Branch's important strengths, including its highly productive investigators, relevant research on important issues for public health, and valuable contributions to its respective fields. The BSC lauded the Branch's mentoring, communication, and leadership and noted that the constant effort to recruit staff to the Branch seemed to take focus away from its research. In addition, the BSC recommended that the PRB hire additional permanent senior-level researchers (at both the tenure-track and staff scientist levels) to provide more continuity and consistency, and that it develop a plan to fully analyze the large datasets available to the Division as a part of the successful completion of research contracts.

PROGRESS AND FUTURE DIRECTIONS FOR THE DIVISION

The Division has remained highly productive since its last report to Council in 2005 and since the last BSC review in 2008. The Division, its staff, and its research are well known and respected within the scientific community in the United States and abroad. As noted by the BSC, the Division consistently designs and completes research addressing critical data gaps within its mission. Furthermore, its staff present and publish research in high-impact journals appropriate for targeted audiences and receive various research awards, including those bestowed upon research fellows. Division staff also field extensive requests for service, including the translation of research for public- or clinical-policy initiatives. Recruitment efforts for new Branch chiefs, investigators, and staff scientists receive good response, and the Division has become a training destination for graduate and professional students.

The Division filled two vital senior leadership positions in 2009: Dr. Paul Albert became the chief of the BBB in July; and, in November, Dr. Germaine Buck Louis was appointed as director of the Division after serving as acting director since 2007. With much of its senior leadership in place (pending recruitment of an EB chief later this year), the Division is already engaging in

concerted strategic planning. This effort includes revisiting the Division's name and identity, vision, and research goals and objectives for the next one, three, and five years.

By design, the Division's research takes years to complete, particularly when working at the population level. But the Division remains committed to tackling some of the most challenging research questions within its mission and to initiating new and innovative projects as current efforts are completed. Likewise, to continue its ability to respond to critical data gaps and emerging public health concerns, Division members will remain professionally active, including participation in national and global discussions on emerging public health issues. Division staff will continue to provide IRTA fellows and summer interns with unique opportunities to utilize original research for dissertations or research experiences, and to mentor them throughout their professional careers. Because the Division takes its commitment to the translation of its research findings quite seriously, it will continue to provide the necessary service for disseminating its work, a recognition of the important intersection between public health and public policy.

More specifically, and within the context of the BSC review and recommendations, the Division will consider the following research directions during the next four years:

- Continue to tackle the most pressing research questions affecting the health and well-being of the population, including clinical populations, within the context of the Division's mission.
 - o In the next few years, the Division will complete several high-impact studies, which will answer questions such as:
 - o Does low-dose aspirin usage reduce the risk of miscarriage?
 - o Do endocrine-disrupting chemicals adversely affect sensitive markers of human reproduction and development?
 - o What does a new labor curve for modern obstetrics look like?
 - o Can parent-report screening tools for neurodevelopmental problems be successfully integrated into routine clinical practice?
 - o What behavioral interventions will prevent automobile crashes among teenagers?
 - o What behavioral interventions will ease the transfer of Type 1 diabetes management activities from parent to child?
- Delineate the immediate and long-term resources required for achieving success.
 - o The Division requires additional investigators to ensure that Branches can accomplish their goals. These positions would include tenure-track investigators for the EB and the PRB, and an additional tenure-track or tenured investigators to lead the bioinformatics component, given the large amount of genomics and proteomics research from the EB and the extensive imaging data from both the EB and PRB.
 - o The Division is assessing how best to retain some of its highly productive IRTA fellows, particularly those who have complementary expertise, for large multifaceted research projects.
 - o To address emerging research questions, the Division will need to utilize some of its many banked biospecimens, meaning that committed laboratories will need to be established. The Division is currently preparing an IDIQ laboratory support contract to enable Division researchers to access banked biospecimens in a timely manner.
 - o Another avenue for leveraging resources is partnering with the extramural research community to pool cohorts from previous studies. For example, growing evidence

suggests that gynecologic or gravid diseases might actually be in the pathway to later onset-adult diseases. Pooling reproductive-age women for followup could help to identify later-onset adult diseases and further elucidate the disease pathway. This type of research is known as life-course epidemiology and is currently challenging the paradigm of studying diseases in isolation.

- De-emphasize research areas that have run their course or that fall outside the mission or expertise of the Division.
 - The Division will be ending its focus on injury research, given the departure of investigators who initiated such projects.
 - In keeping with Division expertise, the EB will not initiate new research that is strictly laboratory based.
 - The PRB has discontinued its intervention research on adolescent problem behavior to concentrate on other research areas. Moreover, the last of several randomized trials on the Checkpoints Program will be completed in 2010 and no further research on this topic is anticipated.
 - The D.C. Initiative will end in early 2010.
- Ensure the timely dissemination of Division research with the goal of promoting public health, especially within special populations.
 - The Division remains committed to and excited about conducting research with the widest range of implications for the populations it serves.
 - As the public's expectations for individualized health and preventive care continue to grow, the Division's etiologic research findings will require translation, so that prediction models can be developed to address critical health care needs.
 - The Division's behavioral researchers remain committed to achieving study goals despite the difficult nature of changing behavior, especially among children and adolescents.

In summary, the Division remains committed to fulfilling its research mission and looks forward to addressing the challenges to come.

Progress and Future Research Directions for the BBB

The BBB has made significant progress in addressing the BSC's comments since its review. As mentioned, Dr. Paul Albert was recruited to be the Branch chief in July 2009. His research expertise and experience make him well qualified to lead the group in developing statistical methods within the context of important scientific problems relevant to the mission of the NICHD. He is also actively involved in Division strategic planning efforts and is currently working with the Division director to coordinate the onsite statistical support contract and to better integrate it within the activities of the BBB. The Branch also recruited two tenure-track investigators, bringing its number of full-time employees to eight, and three IRTA postdoctoral fellows, who augment the Branch's statistical expertise.

The Branch has also taken steps to foster closer interactions between methodological and collaborative research. By organizing working groups, investigators can focus on particular research themes related to the mission of the Division. For instance, BBB staff and EB staff have organized a working group on fetal growth and fecundity determinants and modeling; this

group meets regularly to exchange ideas about methodological and collaborative research using longitudinally collected ultrasound measurements to characterize fetal growth and predict abnormal birth outcomes. A similar working group on jointly modeling longitudinal and survival data is in its beginning phases and includes statisticians from other NIH biostatistics groups. Active collaborations with the PRB are also underway, particularly on the teen driving studies and the diabetic intervention trials, projects that provide BBB investigators with avenues for developing new statistical methods to solve important problems in longitudinal data analysis and clinical trials design. With quantitative investigators in the EB, a number of BBB staff members and fellows organized an external working group on developing new methodology for efficiently designing and analyzing genes, environment, and gene-environment interactions, when measures of gene and environment effects are taken from new innovative biomarkers. Papers from this working group were recently accepted for a special *Statistics in Medicine* volume, which will be edited by Dr. Paul Albert and Dr. Enrique Schisterman (from EB).

BBB investigators are also taking on roles within statistical and/or epidemiologic organizations, organizing and giving invited presentations at national meetings, and mentoring students and postdoctoral fellows.

More specifically, and within the context of the BSC review and recommendations, the BBB will consider the following research directions during the next four years:

- Fully integrate the Branch's independent research programs into the research programs of the Division.
 - Collaborate with all EB and PRB investigators to develop synergistic relationships between collaborative and independent methodological research.
 - Investigate strategies for increased collaborations with investigators outside the Division, including those in the NICHD Division of Intramural Research and in the extramural community.
- Augment the Branch with expertise in the analysis of high-dimensional genetics and imaging data. Recruiting such expertise is a high priority, especially for developing new techniques to analyze the unique proteomic and micro-array data from the LIFE and ENDO Studies, and the ultrasound imaging data from the National Standard in Normal Fetal Growth Study.
- Increase the number of summer students and predoctoral and postdoctoral fellows to become a leader in training future statistical scientists interested in human reproduction and development across the lifespan.
- Increase the visibility of the BBB within the biostatistics community by organizing and participating in an increased number of invited sessions at national and international biostatistics meetings, and by fulfilling various roles in leading statistics and biostatistics organizations.
- Focus on biostatistics research related to problems in the Division and the Institute to become a leader among NIH biostatistics groups in research areas central to the Division. The Branch's aims to become a key destination for statistical scientists interested in the areas of longitudinal data analysis, survival analysis, and the interface between longitudinal data and high-dimensional genetics and imaging-data analysis. Within this context, the Branch will consider developing:

- o New methods for evaluating the effect of environmental factors on hormonal menstrual cycle patterns;
- o Joint models for multivariate longitudinal data and time-to-event data;
- o New longitudinal modeling approaches, based on longitudinal measurements, for identifying abnormal fetal growth;
- o Innovative approaches for analyzing high-dimensional bioinformatics data from longitudinal studies;
- o New analytic approaches to account for compliance in longitudinal dietary trials;
- o New methodology for assessing diagnostic accuracy and measures of agreement in longitudinal studies; and
- o Predictive modeling approaches for identifying individuals at high risk for poor fetal outcomes and infertility (with the EB), and for identifying poor teenage-driving performance (with the PRB).

Progress and Future Research Directions for the EB

The EB's presence as a preeminent government research entity for reproductive, perinatal, and pediatric research—including the design and successful conduct of original and collaborative research—has remained strong during the reporting period. At the same time, the EB provides a unique forum for training and mentoring the next cadre of epidemiologists and for serving Branch members' respective professions. The Branch continues to design, implement, and complete original research using novel technologies (including those developed by the Branch) in response to critical data gaps. Given the Branch's limited size, its staff has become adept at prioritizing selected research areas, such as the genetic and environmental determinants of adverse reproductive and developmental outcomes, including diseases that arise during pregnancy and that have implications for mothers and fetuses.

In 2009, the Branch completed the data acquisition and management for three studies: the ENDO Study, the LIFE Study, and Safe Labor Consortium; these efforts provide the world's only data source for these unique situations and include available biospecimen banks (for the first two studies). Three additional projects—the EAGeR Trial, the Genetic Determinants of Birth Defects Studies, and the Upstate KIDS Study are ongoing and should be completed during the next several years. As these efforts end, the Branch will begin new projects on other topics. For instance, the EB will implement an IDIQ laboratory support contract in fiscal years 2010 and 2011 to allow the prompt analysis of banked biospecimens for addressing promising new leads (e.g., microbiology of BV). The Branch will also begin at least two major research contracts on the following topics: a retrospective cohort study focusing on the etiologic (gene-environmental) determinants underlying the progression of GDM to Type 2 diabetes, and an in-depth assessment of ART and embryonic/fetal health.

More specifically, and within the context of the BSC review and recommendations, the EB will consider the following research directions during the next four years:

- Recruit additional expertise and leverage resources to expand the Branch's research abilities.
 - o To fulfill its research mission, the Branch requires additional expertise in genetics, various “-omics” (such as proteomics), reproductive epidemiology, and in other areas identified through retreats and strategic planning sessions.

- o The Branch is in the process of a full and open search for a new Branch chief and will require at least one additional tenure-track fellow in each of the next three years.
- o Branch- and Division-wide planning is also underway to identify career development options for fellows, including appointments as research fellows, staff scientists, and tenure-track investigators.
- o Branch members will continue serving their professional communities, while being cognizant of new opportunities, such as training programs or special symposia, and leveraging resources with outside entities when appropriate.
- Continue efforts to remain a top research entity for reproductive, perinatal, and pediatric epidemiologic research.
 - o In response to growing evidence delineating the early origins of disease, the Branch is designing life-course epidemiologic projects such as:
 - o Understanding the etiologic (genetic and environmental) determinants underlying the progression of GDM to Type 2 diabetes, and identifying prevention strategies through behavior modification; and
 - o Understanding the causal pathway between gynecologic disorders, gravid health status, and later-onset adult chronic disorders; for example, polycystic ovary syndrome could predispose a woman to preeclampsia, which might be in the pathway to metabolic syndrome and Type 2 diabetes; similarly, endometriosis might reduce the likelihood of gravid disorders, but increase the onset of autoimmune and reproductive cancers.
 - o An exciting aspect of future research is the assessment of maternal, paternal, and parental exposures and adverse reproductive and developmental outcomes.
 - o This avenue of research is unique in that it utilizes a couple-based design for assessing couple-dependent outcomes, such as conceptions or pregnancies. This type of research will be instrumental in determining paternally, maternally, or couple-mediated effects on human reproduction and development.
 - o Such efforts are relevant for the analysis of treatments, such as ART (as in the Upstate KIDS Study) and chemicals and behaviors (as in the LIFE Study).
 - o Address other promising areas of research, including (but not limited to):
 - o Identifying the role of low-dose aspirin in preventing miscarriage; if found efficacious and safe, this remedy could allow an inexpensive treatment for the approximately 15 percent to 20 percent of pregnant women who experience pregnancy losses;
 - o Establishing the labor curve for modern obstetrical populations to replace the one developed in the 1950s and, possibly, allow women to labor longer without the iatrogenic risk of cesarean delivery;
 - o Establishing fetal growth standards for singleton and twin pregnancies in the United States to aid clinicians in screening for intrauterine growth restriction, macrosomia, or other altered growth states;
 - o Determining the onset and progression of specific angiogenetic and other emerging molecules in the development of pregnancy complications, such as preeclampsia and hypertension, to create prediction models for clinical use; and
 - o Identifying genetic and environmental determinants of birth defects.

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- Design studies that encompass “-omics” research areas and technology, including use of banked specimens for building upon existing or completed research.
 - The extreme rapidity in which “-omics” research and imaging-related technologies are expanding, coupled with declining costs, makes it appealing from both innovation and cost-effectiveness perspectives. For example:
 - The ENDO Study initiated a proteomics component to identify protein patterns for gynecologic disorders (including endometriosis) by choice of media (i.e., omentum fat, peritoneal fluid, urine), given the difference in protein expression by tissue type.
 - The LIFE Study designed a follow-on component to assess spermatozoal RNAs in relation to proven male fecundity to identify predictors of male fecundity.
 - The extensive MRI and 3-D ultrasound imaging data obtained from the ENDO Study and the Normal Fetal Growth Study provide an exciting forum for the analysis of high-dimensional data to aid in better clinical prediction models.
 - Other laboratory advances that impact Branch work include technologies for extracting DNA from banked newborn blood spots and the analysis of such blood spots for cytokines and toxicologic biomarkers.
- Continue to publish Branch research and work to integrate research findings into public- or clinical-policy discussions.
 - The EB supports and encourages the interface between public health and policy by ensuring that all relevant target audiences are aware of Branch research findings, to the extent permissible for federal employees. For example:
 - Branch work on the clinical management of the parturient woman has important implications for American College of Obstetricians and Gynecologists clinical guidelines.
 - The AAP used findings from Branch research on drowning to revise its policy for the prevention of drowning (policy is currently in embargoed draft form).
 - Branch infertility and child health research has implications for both practicing gynecologists and for the Society for Assisted Reproductive Technology.
 - Research findings on environmental chemicals in the context of lifestyle are directly relevant to the U.S. Environmental Protection Agency.
 - Branch methodologic research has produced promising new study hybrid (pooling) designs, which are applicable to both epidemiologic and clinical research when resources are limited or when biospecimens need to be conserved.
 - Efforts on statistical handling of laboratory measurements below the laboratory limits of detection or in avoiding the automatic adjustment of concentrations for lipids or creatinine when assessing health outcomes are now becoming mainstream across disciplines and should help minimize bias in published research.

As public health continues to gain academic and research stature and increased public recognition, the EB recognizes the expectation to improve health, specifically, individual health and is poised to meet these expectations. By continuing to focus on reproductive health, empirically based clinical management of the parturient woman, and the health of infants and children, the Branch will advance its mission while also serving the publics that support it.

Progress and Future Research Directions for the PRB

Since the BSC review and the last presentation to the NACHHD Council, the PRB has made significant progress in addressing goals and recommendations. The Branch established a permanent position for Dr. Ron Iannotti, ensuring that his important research expertise remains a resource to the Branch. The Branch's portfolio has grown in both the number and intensity of studies included. The portfolio includes a new strategic focus on family management of childhood diabetes, consistent with the research interests of a number of Branch staff. The quality and quantity of the Branch's peer-reviewed papers nearly doubled from 41 (for the 2000-2004 period) to 71 (for the current reporting period), despite having essentially the same number of staff. (See [Appendix C](#) for a listing of Branch publications.)

The Branch's three well-established research areas each include a systematic set of studies that reflect a combination of strategic planning and success from entrepreneurial efforts. This research employs cutting-edge methodology and addresses issues of public health importance. PRB research includes an emphasis on translation; for instance, data from field studies on driving can inform licensing policy, and current research on family management of childhood diabetes is evaluating the utility of a clinic-linked intervention.

More specifically, and within the context of the BSC review and recommendations, the PRB will consider the following research directions during the next four years:

- Enhance Branch expertise and leverage resources. Organizationally, the Branch is very small, particularly relative to the number and magnitude of the studies it conducts. In addition to planning for leadership succession within the Branch and supporting tenure for Branch investigators, the Branch also plans to hire at least one tenure-track investigator.
- Continue to address interesting research questions of public health importance and include efforts in translational research. Within the Branch's three research areas, such efforts might address the following research questions:
 - o Young Driver Studies
 - o What factors (e.g., risky driving, second-task engagement, teenage passengers) are associated with crashes among newly licensed teenage drivers?
 - o How does novice teen driving performance and risk (including crash risk, driving skill, and aggressive driving) vary over the first 18 months of licensure under high-risk driving conditions (e.g., with teen passengers, at night, while engaging in secondary task)?
 - o How do novice teenagers develop driving proficiency during the first 18 months of licensure?
 - o How do the characteristics of teenage passengers affect teenage driving performance under various driving conditions?
 - o What are the implications of findings on novice teen driving performance for licensing policy?
 - o To what extent can the Checkpoints Program be disseminated, and what are its effects on teenage driver outcomes?
 - o Does integration of the Checkpoints Program beyond 18 months further reduce crashes and enhance teen driving?

- o Adolescent Health Behavior Studies
 - o What trends are detectable in diet, physical activity, substance use, and other adolescent health behaviors in the United States between 1998 and 2009?
 - o What individual, family, school, social, and environmental factors (e.g., access to recreational resources, walker/biker-friendly neighborhoods) can promote or sustain positive health, positive health behaviors, and mental health?
 - o What are the trajectories of adolescent health behaviors, including healthful diet, physical activity, illicit substance use, dating violence, and health status (i.e., obesity, metabolic syndrome, and injuries from motor vehicle crashes or dating violence) from adolescence through the post high-school year?
 - o Are there significant transition points in adolescent health risk behaviors and risk indicators?
 - o How do changes in individual, family, school, and social arena/environment relate to developmental changes in diet, physical activity, substance use, dating violence, risky driving, and other health risk factors?
 - o What is the role of social networks in obesity and substance use, and what is the direction of causal pathways for peer selection and peer influence?
 - o What gene-behavior interactions might serve as the basis for interventions for those identified as at risk for obesity or substance use?

- o FMOD Studies
 - o What is the effect of the FMOD clinic-integrated family-based behavioral intervention on diabetes management, glycemic control, and quality-of-life?
 - o Is the FMOD intervention differentially effective for youth of different ages, socioeconomic status, or duration of diabetes?
 - o To what extent does the FMOD intervention impact parenting behaviors related to diabetes management, and to what extent does the intervention account for the effects on diabetes outcomes?
 - o To what extent does dietary intake affect glycemic control and other diabetes-related outcomes?
 - o What youth, parent, and family factors influence the healthfulness of dietary intake?
 - o What is the effect of the CHEF behavioral nutrition intervention on dietary intake, glycemic control, and other diabetes-related outcomes?
 - o Is adoption of a healthier diet associated with a change in family food costs?

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FIGURES AND TABLES

TABLE 1: DIVISION OF EPIDEMIOLOGY, STATISTICS, AND PREVENTION RESEARCH BY BRANCH, FISCAL YEAR 2005 THROUGH FISCAL YEAR 2009

Table 1A: Office of the Director

Name	Title	Appointment Date and Departure Date (New Position/Location)
Germaine M. Buck Louis, Ph.D., M.S.	Acting Director/Director	2007/2009
Mark A. Klebanoff, M.D., M.P.H.	Director	1982-2007 (Epidemiology Branch)
Adrienne Lonaberger	Program Analyst	2007
Computer Sciences Section		
Ann Trumble, Ph.D.	Chief, Computer Sciences Section	1992
Patricia Moyer, B.S.	Information Technology (IT) Specialist	1991
Collaborative Studies Unit		
Michele Kiely, Dr.P.H.	Chief, Collaborative Studies Unit	2002
Maurice Davis, M.S.	Health Scientist Administrator	2002

Table 1B: Biostatistics & Bioinformatics Branch (BBB)

Name	Title	Appointment Date and Departure Date (New Position/Location)
Paul Albert, Ph.D.	Chief and Senior Investigator	2009
Zhen Chen, Ph.D.	Tenure-track Investigator	2009
Christopher Cox, Ph.D.	Senior Research Fellow	2002-2005 (John Hopkins University)
Sung Duk Kim, Ph.D.	Research Fellow	2008
Aiyi Liu, Ph.D.	Senior Investigator	2002
Rajeshwari Sundaram, Ph.D.	Tenure-track Investigator	2006
James Troendle, Ph.D.	Senior Investigator	1992
Kai Fun Yu, Ph.D.	Senior Investigator	1990
Zhiwei Zhang, Ph.D.	Tenure-track Investigator	2009

Table 1C: Epidemiology Branch (EB)

Name	Title	Appointment Date and Departure Date (New Position/Location)
Germaine M. Buck Louis, Ph.D., M.S.	Chief and Senior Investigator	2000-2009 (Division Director)
Ruth A. Brenner, M.D., M.P.H.	Tenure-track Investigator	1999-2006 (National Children's Study)
Zhen Chen, Ph.D.	Staff Scientist	2008-2009 (BBB)

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Name	Title	Appointment Date and Departure Date (New Position/Location)
Mary R. Conley, M.A.	IT Specialist	1991
Mary L. Hediger, Ph.D.	Biologist and Acting Chief	1999/2009
Jagteshwar Grewal, Ph.D., M.P.H.	Staff Scientist	2007
Mark A. Klebanoff, M.D., M.P.H.	Senior Investigator	2008
Richard J. Levine, M.D., M.P.H.	Senior Investigator	1991
Feng-Ying (Kimi) C. Lin, M.D., M.P.H.	Medical Officer	1993-2006 (NICHD Division of Intramural Research)
Courtney D. Lynch, Ph.D., M.P.H.	Staff Scientist	2004-2008 (Ohio State University)
James L. Mills, M.D., M.S.	Senior Investigator	1979
Neil Perkins, Ph.D., M.A.	Staff Scientist	2008
Gitanjali Saluja, Ph.D.	Research Fellow	2004-2006 (Westat)
Enrique F. Schisterman, Ph.D., M.A.	Senior Investigator	2002
Ondine von Ehrenstein, Ph.D.	Tenure-track Investigator	2007-2008 (University of California, Los Angeles)
Cuilin Zhang, M.D., Ph.D.	Tenure-track Investigator	2007
Jun (Jim) Zhang, M.D., Ph.D.	Senior Investigator	1997

Table 1D: Prevention Research Branch

Name	Title	Appointment Date and Departure Date (New Position/Location)
Bruce Simons-Morton, Ed.D., M.P.H.	Chief and Senior Investigator	1992
Denise Haynie, Ph.D., M.P.H.	Staff Scientist	2000
Ronald Iannotti, Ph.D.	Staff Scientist	2001
Tonja Nansel, Ph.D.	Tenure-track Investigator	2001
Marie-Claude Ouimet, Ph.D.	Research Fellow	2008-2009 (McGill University)
Jing Wang, Ph.D.	Research Fellow	2009

NOTE: All tables exclude Intramural Research Training Award fellows or individuals in other mentee positions.

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TABLE 2: DIVISION OPERATING AND CONTRACT BUDGETS, FISCAL YEAR 2005 THROUGH FISCAL YEAR 2010 (IN THOUSANDS OF U.S. DOLLARS)

	Fiscal Year 2005	Fiscal Year 2006	Fiscal Year 2007	Fiscal Year 2008	Fiscal Year 2009	Fiscal Year 2010	Percent Net Change
Operating Budget							
Salary*	\$4,490	\$4,843	\$5,159	\$4,992	\$5,706	\$6,501	30 % (2008) 14 % (2009)
Other**	\$940	\$891	\$987	\$553	\$435	\$435	-21 % (2008) 0 % (2009)
Total (# of Full Time Equivalents)	\$5,430 (25)	\$5,734 (25)	\$6,146 (26)	\$5,545 (28)	\$6,141 (30)	\$6,936 (31)	NA
	Fiscal Year 2005	Fiscal Year 2006	Fiscal Year 2007	Fiscal Year 2008	Fiscal Year 2009	Fiscal Year 2010	Percent Net Change
Contracting Budget	\$13,998	\$12,067	\$14,900	\$15,650	\$14,488	\$13,800	NA

NOTE: Operating budget reflects the operating expenses for the Division. Contract budget reflects the Research and Development (R&D) and support contracts for the Division.

* Includes salaries, benefits, Intramural Research Training Award (IRTA) fellows, and summer interns.

** Includes all non-salary and benefits-related expenditures (e.g., travel, software, furniture rentals); excludes funding for onsite programming support, which is funded through the contract budget.

TABLE 3: DISTRIBUTION OF DIVISION CONTRACT FUNDING BY BRANCH AND INVESTIGATOR, FISCAL YEAR 2005 THROUGH FISCAL YEAR 2009

Table 3A: Office of the Director

Principal Investigator (Project)	Fiscal Year 2005	Fiscal Year 2006	Fiscal Year 2007	Fiscal Year 2008	Fiscal Year 2009
Trumble (Programming Support)	\$879,127	\$931,279	\$986,528	\$2,368,728	\$104,011
Trumble (Biospecimen Repository)	\$405,128	\$699,004	\$281,556	\$300,000	\$487,548
Division Total	\$12,430,891	\$12,066,903	\$14,900,228	\$15,639,101	\$14,487,617

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Table 3B: Biostatistics & Bioinformatics Branch

Principal Investigator (Project)	Fiscal Year 2005	Fiscal Year 2006	Fiscal Year 2007	Fiscal Year 2008	Fiscal Year 2009
Albert (Indefinite Delivery, Indefinite Quantity Data Coordinating Center Support)				\$400,000	\$446,272
Division Total	\$12,430,891	\$12,066,903	\$14,900,228	\$15,639,101	\$14,487,617

Table 3C: Epidemiology Branch

Principal Investigator (Project)	Fiscal Year 2005	Fiscal Year 2006	Fiscal Year 2007	Fiscal Year 2008	Fiscal Year 2009
Brenner (Swim Lessons)	\$425,941				
Brenner (Injuries among Disabled)		\$320,000	\$400,000		
Louis (Longitudinal Investigation of Fertility and Environment Study)	\$1,689,707	\$1,333,125	\$3,811,192	\$26,051	\$573,259
Louis (Endometriosis: Natural History, Diagnosis and Outcomes Study)		\$1,725,792	\$1,195,395	\$2,110,000	\$327,796
Hediger (Upstate New York Infant Development Screening Study)			\$790,889	\$2,586,003	\$1,491,452
Levine (Lab Support)		\$723,415			
Levine (Pregnancy Complications)					\$587,440
Mills (Irish Birth Defects Study)	\$100,000	\$337,000	\$100,000	\$100,000	
Mills (Genetic Birth Defects)			\$403,106	\$1,418,847	\$175,517
Mills (Irish, Genome-wide Association Studies of Defects)					\$500,000
Saluja/Brenner (Injuries)	\$25,000	\$25,000			
Schisterman (BioCycle Study)	\$1,567,067				
Schisterman (Effects of Aspirin in Gestation and Reproduction Trial)		\$1,978,424	\$3,289,369	\$2,347,827	\$2,728,280
J. Zhang (Safe Labor Consortium)		\$404,189	\$2,588,547	\$287,255	
J. Zhang (National Standard of Normal Fetal Growth)				\$691,284	\$3,433,689
Division Total	\$12,430,891	\$12,066,903	\$14,900,228	\$15,639,101	\$14,487,617

Table 3D: Prevention Research Branch

Principal Investigator (Project)	Fiscal Year 2005	Fiscal Year 2006	Fiscal Year 2007	Fiscal Year 2008	Fiscal Year 2009
Iannotti (Health Behavior in School Children Survey)	\$1,406,914	\$230,146		\$501,741	\$1,885,289
Nansel (Family Management of Diabetes)	\$3,920,415	\$1,823,515		\$1,012,167	
Nansel (Cultivating Healthy Eating in Families Study)			\$406,570	\$848,884	\$942,982
Simons-Morton (Young Drivers)	\$171,050				
Simons-Morton (Violence Prevention)	\$355,326	\$299,000			
Simons-Morton (Crash Risk)	\$794,470	\$1,237,014	\$139,708		\$225,000
Simons-Morton (Effective Drivers)	690,746		\$507,368	\$650,889	
Simons-Morton (G-Force Events)					\$423,413
Division Total	\$12,430,891	\$12,066,903	\$14,900,228	\$15,639,101	\$14,487,617

TABLE 4: BIostatISTICS & BIOINFORMATICS BRANCH, KEY INVESTIGATOR-INITIATED RESEARCH PROJECTS

Methodologic Research	Research Goals	Investigator(s)
Joint Modeling of Time-to-Event and Multivariate Longitudinal Data	Develop statistical methodology for jointly modeling moderate- or high-dimensional longitudinal data (e.g., panel of cytokines) and an event time (i.e., time to ovulation).	Albert
Modeling Longitudinal Menstrual Cycle Data	Develop new statistical methodology for analyzing multivariate longitudinal biomarkers measured over the menstrual cycle; of particular interest are new methods for jointly modeling menstrual cycle patterns and cycle length.	<ul style="list-style-type: none"> • Albert • Schisterman (Epidemiology Branch [EB])
Modeling Correlated Survival Data with Competing Risks	Develop statistical methodology for analyzing correlated event-time data with competing risks; motivated by Division studies examining association between the occurrence and time of pregnancy complications across a woman's multiple pregnancies.	<ul style="list-style-type: none"> • Albert • Sundaram • J. Zhang (EB)
Markov Modeling from Retrospective Samples	Develop new statistical methodology for the design and analysis of studies that examine the relationship between biomarkers and a recurrent binary process (e.g., recurrent patterns of bacterial vaginosis) when the number of biomarker measurements is a limitation due to the expense of the assay.	<ul style="list-style-type: none"> • Albert • Yu • Klebanoff (EB)

Methodologic Research	Research Goals	Investigator(s)
Modeling Longitudinal/Correlated Data with an Informative Number of Measurements	Develop new statistical methods for analyzing longitudinal data when the number of measurements depends on the response process; motivated by fetal growth studies in EB and the driving studies in Prevention Research Branch (PRB).	<ul style="list-style-type: none"> • Chen • Albert • Zhang (Intramural Research Training Award [IRTA] Fellow)
Inter-observer Agreement	Develop new analytical methods for estimating inter-observer agreement in the diagnosis of endometriosis when clinical information is sequentially augmented.	<ul style="list-style-type: none"> • Chen • Buck Louis (EB) • Zhang (IRTA Fellow)
Copy-number Variations	Develop methods to analyze genome-wide copy-number variations and investigate the relationship between copy number variation and disease phenotype.	Chen
Bayesian Methods	Develop new Bayesian fecundability models and propose Bayesian procedures for comparing and averaging random effects models.	<ul style="list-style-type: none"> • Chen • Louis (EB)
Bayesian Cure Rate Model for Survival Data	Develop a general class of models to incorporate a cure fraction by introducing the latent variables.	Kim
Statistical Methods for Biomarker Studies	Develop efficient statistical methods for the design and analysis of biomarker studies; examples include efficient designs for pooling samples and new techniques for accounting for data with detection limits.	<ul style="list-style-type: none"> • Liu • Albert • Z. Zhang • Schisterman (EB) • Liu (IRTA Fellow)
Sequential and Adaptive Methods in Medical Research	Develop sequential and adaptive methods useful for medical research related to diagnostic biomarkers, receiver-operating characteristic (ROC) curves, and clinical trials.	<ul style="list-style-type: none"> • Liu • Liu (IRTA Fellow) • Yu
Statistical Methods for Mendelian Randomization in Case-control Studies	Develop methods to use genetic polymorphisms as instrumental variables to estimate causal effects of exposure on disease.	<ul style="list-style-type: none"> • Liu • Liu (IRTA Fellow) • C. Zhang (EB)
Complex Models: Beyond Cox's Model	Develop new statistical methods to assess time-varying effects of exposures and to accommodate general type of hazards (i.e., crossing over) between exposure group versus non-exposure group.	<ul style="list-style-type: none"> • Sundaram • McLain (IRTA Fellow)
Modeling Techniques for Assessing Human Fecundity	Develop joint modeling approaches for time to (multiple) pregnancy by incorporating proper dependency structure to account for correlated longitudinal data.	<ul style="list-style-type: none"> • Sundaram • Buck Louis (EB) • Kim (IRTA Fellow) • Lum (IRTA Fellow)
Recurrent Events	Develop statistical methods for analyzing outcomes of repetitive nature (e.g., repeated pregnancies, repeated increase in dilation by unit) in presence of informative censoring.	<ul style="list-style-type: none"> • Sundaram • J. Zhang (EB)
Multistage Models	Develop stage-occupation probabilities and assess risks of events in complex biomedical processes having different stages and/or outcomes (i.e., labor progression).	Sundaram

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Methodologic Research	Research Goals	Investigator(s)
Multiple Comparison Procedures for Multiple Outcome Data	Develop methods of multiple comparisons for situations in which many outcome measures are tested on the same set of individuals; motivated by genetic data that typically contains multiple single nucleotide polymorphisms to be compared simultaneously.	Troendle
Methods of Genetic Association Testing	Develop methods of testing for genetic association; emphasis on triad studies, which collect genetic data from children and their parents; motivated by the Irish Birth Defects Study Group in which triad data is used in genetic association analysis.	<ul style="list-style-type: none"> • Troendle • Yu • Mills (EB)
Nonparametric Comparison of Populations	Develop and compare robust methods of hypothesis testing and estimation while accounting for other factors; motivated by data from the Irish Birth Defects Study Group, which sought to compare two groups while accounting for gender.	<ul style="list-style-type: none"> • Troendle • Yu
Longitudinal Data Analysis	Develop and study models for longitudinal data collected for Division studies, including the Successive Small-for-Gestational Age Studies I and II, the Longitudinal Study of Vaginal Flora, and secondary studies on Calcium for the Prevention of Preeclampsia.	<ul style="list-style-type: none"> • Yu • Liu
Methods for Analyzing High-dimensional Continuously Collected Longitudinal Data in Small Samples	Develop and compare statistical methods for analyzing data from teen driving studies which involve a small number of subjects who are followed continuously for a long period of time.	<ul style="list-style-type: none"> • Zhang • Albert • Simons-Morton (PRB) • Wang (PRB)

TABLE 5: EPIDEMIOLOGY BRANCH, KEY INVESTIGATOR-INITIATED RESEARCH PROJECTS

Table 5A: Reproductive Epidemiologic Research

Project Title	Research Goals	Principal Investigator (Listed First) and Co-investigators
Longitudinal Investigation of Fertility and Environment (LIFE) Study	Determine the impact of persistent environmental chemicals in the context of people’s lifestyles on human reproduction and development; assess maternal, paternal, and parental exposures during sensitive windows of human development; and develop modeling strategies for chemical mixtures.	<ul style="list-style-type: none"> • Buck Louis • Chen (Biostatistics & Bioinformatics Branch [BBB]) • Gollenberg (Intramural Research Training Award [IRTA] Fellow) • Kim (BBB) • McLain (BBB IRTA Fellow) • Schisterman • Sundaram (BBB)
<u>Endometriosis: Natural History, Diagnosis and Outcomes (ENDO) Study</u>	Determine if hormonally active environmental agents and other naturally occurring compounds are involved in the pathophysiology of endometriosis; determine if the agents are specific to endometriosis or gynecologic disorders in general; determine the validity and reliability of endometriosis diagnoses; and utilize proteomics analysis to identify biochemical pathways underlying endometriosis.	<ul style="list-style-type: none"> • Buck Louis • Chen (BBB) • Cooney (IRTA Fellow) • Hediger • Sundaram (BBB) • Trumble (Office of the Director [OD])
BioCycle Study	Determine the relation between sex hormones on biomarkers of oxidative stress and antioxidant status during the menstrual cycle.	<ul style="list-style-type: none"> • Schisterman • Albert (BBB) • Gaskins (IRTA Fellow) • Hediger • Liu (BBB) • Mumford (IRTA Fellow) • Perkins • Pollack (IRTA Fellow)
<u>Effects of Aspirin on Gestation and Reproduction (EAGeR) Trial</u>	Assess the efficacy and safety of low-dose aspirin and folic acid on the prevention of early pregnancy failure and later pregnancy events compared to folic acid alone.	<ul style="list-style-type: none"> • Schisterman • Gaskins (IRTA Fellow) • Hediger • Mumford (IRTA Fellow) • Perkins • Yeung (IRTA Fellow) • C. Zhang
Genome-wide Association Study of Abdominal Adiposity in Women	Identify genome-wide genetic signals which may predispose to abdominal adiposity.	<ul style="list-style-type: none"> • C. Zhang • Bowers (IRTA Fellow) • Hu (Harvard University) • Yeung (IRTA Fellow)
Studies of Bacterial Vaginosis	Understand the pathogenesis of bacterial vaginosis; explore its association with adverse pregnancy outcomes.	<ul style="list-style-type: none"> • Klebanoff • Nansel (Prevention Research Branch [PRB]) • Yu (BBB) • J. Zhang

Table 5B: Perinatal Epidemiologic Research

Project Title	Research Goals	Principal Investigator (Listed First) and Co-investigators
Growth Factors and Preeclampsia	Determine the roles of growth factors and their inhibitors in the pathogenesis, prediction, and treatment of preeclampsia.	<ul style="list-style-type: none"> • Levine • Yu (BBB)
Pathogenesis of Preeclampsia/Gestational Diabetes Mellitus (GDM) in Women with Chronic Hypertension or Obesity	Determine the molecular bases of preeclampsia and GDM and molecular interactions important to both conditions.	<ul style="list-style-type: none"> • Levine • C. Zhang • Klebanoff • Yu (BBB)
Novel Metabolic Biochemical Markers and GDM (Incorporated into National Standard of Normal Fetal Growth Study and the EAGeR Trial)	Collect longitudinal biospecimens for investigating the pathogenesis of GDM; prospectively determine the role of novel metabolic biomarkers (i.e., adipocyte cytokines) in the pathogenesis, prediction, and treatment of GDM.	<ul style="list-style-type: none"> • C. Zhang • Hediger • Schisterman • Yeung (IRTA Fellow) • J. Zhang
Dietary, Lifestyle, and Genetic Risk Factors and GDM	Delineate dietary, lifestyle, and genetic factors in the development of gestational diabetes.	<ul style="list-style-type: none"> • C. Zhang • Bowers (IRTA Fellow) • Yeung (IRTA Fellow)
Transition of GDM to Type 2 Diabetes: Life-course Approach	Identify the gene-environmental determinants underlying the transition of GDM to Type 2 diabetes.	<ul style="list-style-type: none"> • C. Zhang • Buck Louis • Bowers (IRTA Fellow) • Yeung (IRTA Fellow)
Consortium on Safe Labor	Compile a large obstetric-labor-neonatal database with 200,000 births; describe normal labor patterns in the U.S. women; and identify a more appropriate time to perform cesarean delivery in labor protraction and arrest.	<ul style="list-style-type: none"> • J. Zhang • Klebanoff • Troendle (BBB) • Laughon (IRTA Fellow)
National Standard for Normal Fetal Growth Study	Establish a U.S. national standard for normal fetal growth (velocity) and size for gestational age; create an individualized standard for optimal fetal growth; and improve accuracy of fetal weight estimation.	<ul style="list-style-type: none"> • J. Zhang • Grewal • Hediger • Troendle (BBB) • C. Zhang • Z. Zhang (BBB)

Table 5C: Pediatric Epidemiologic Research

Project Title	Research Goals	Principal Investigator (Listed First) and Co-investigators
Birth Defects Research: NICHD Irish Birth Defects Research Group	Determine the pathogenesis of neural tube defects and oral facial clefts.	<ul style="list-style-type: none"> • Mills • Carter (IRTA Fellow) • Conley • Kuehn (IRTA Fellow) • Troendle (BBB)
Genetic Factors in Birth Defects	Look for genetic variants associated with a wide range of birth defects.	<ul style="list-style-type: none"> • Mills • Carter (IRTA Fellow) • Conley • Kuehn (IRTA Fellow) • Troendle (BBB)
NICHD- <i>Universidad de Chile</i> Fetal Alcohol Study	Determine the effects of prenatal exposure to high levels of alcohol in a prospectively identified cohort.	<ul style="list-style-type: none"> • Mills • Carter (IRTA Fellow) • Conley • Kuehn (IRTA Fellow) • Troendle (BBB)
Growth and Maturation in Children with Autism	Determine if children with autism show patterns of growth and maturation that differ from those of control children.	<ul style="list-style-type: none"> • Hediger • Mills • Yu (BBB)
Upstate New York Infant Development Screening (KIDS) Study	Determine, for a cohort of 1,500 infants from Upstate New York identified on birth certificates as having been conceived by infertility treatment (exposed) and 4,500 regionally matched infants (unexposed), if infertility treatment is associated with adverse developmental outcomes through age three years.	<ul style="list-style-type: none"> • Hediger • Buck Louis • Gollenberg (IRTA Fellow) • Sundaram (BBB) • McLain (BBB IRTA Fellow) • Z. Zhang (BBB)
Hormonal Indicators of Pubertal Onset and Their Relationship to Blood Lead Levels: Analyses of Stored Biologic Specimens, for Children Ages 6-11 Years, Third National Health and Nutrition Examination Survey (NHANES III), 1988-1994	Analyze stored biologic specimens (serum) for children, ages six years to 11 years as part of NHANES III: 1988-1994; estimate by hormones (luteinizing hormone and inhibin B for boys and girls, testosterone for boys) timing of the onset of pubertal development in a nationally representative sample of children; and determine what blood lead levels are associated with delayed maturation in girls.	<ul style="list-style-type: none"> • Hediger • Buck Louis • Gollenberg (IRTA Fellow) • Z. Zhang (BBB)
Risk Factors for Childhood Drowning	Assess the relation between swimming lessons for infants and drowning.	<ul style="list-style-type: none"> • Brenner • Klebanoff • Trumble (OD)

Table 5D: Methods Research

Project Title	Research Goals	Principal Investigator (Listed First) and Co-investigators
Methodological Development for Exposure Assessment of New Biomarkers	Evaluate, using causal inference methods, sources of bias and methods to correct exposure assessment.	<ul style="list-style-type: none"> • Schisterman • Albert (BBB) • Liu (BBB) • Malinovsky (IRTA Fellow) • Perkins • Gaskins (IRTA Fellow) • Mumford (IRTA Fellow) • Pollack (IRTA Fellow)
Design and Analysis of Pooled Data	Develop cost-efficient study designs and statistical methods for pooling biospecimens.	<ul style="list-style-type: none"> • Schisterman • Liu (BBB) • Perkins • Albert (BBB) • Malinovsky (IRTA Fellow) • Danaher (IRTA Fellow) • B. Zhang (BBB IRTA Fellow)

NOTE: Restricted to NICHD collaborations except for two recent tenure-track hires.

TABLE 6: PREVENTION RESEARCH BRANCH, KEY INVESTIGATOR-INITIATED RESEARCH PROJECTS

Table 6A: Young Driver Risk Assessment Studies

Project Title	Research Goal	Investigators
Naturalistic Teenage Driving Study	Assess driving performance and crash outcomes during teens' first 18 months of licensure compared to adults; use instrumented vehicles with cameras, global positioning systems, motion sensors, and other related devices.	<ul style="list-style-type: none"> • Simons-Morton • Wang • Pradhan (Intramural Research Training Award [IRTA] Fellow) • Albert (Biostatistics & Bioinformatics Branch [BBB]) • Z. Zhang (BBB)
Cortisol and Driving Performance	Determine the association between cortisol assessment of risk acceptance and test track and naturalistic driving performance.	Simons-Morton
Supervised Practice Driving Study	Assess the nature and amount of parent-supervised practice driving and its effect on independent driving performance upon licensure.	<ul style="list-style-type: none"> • Simons-Morton • Pradhan (IRTA Fellow)
Test Track Evaluation of Novice Teen Driving Performance	Assess novice teen and adult driving performance at teen licensure and six months later on a test track.	<ul style="list-style-type: none"> • Simons-Morton • Pradhan (IRTA Fellow)
Use of Electronic Monitoring Devices	Determine how families use the DriveCam event monitoring device.	<ul style="list-style-type: none"> • Simons-Morton • Pradhan (IRTA Fellow)
Effects of Age and Sex of Passengers on Fatal Crash Rates	Analyze Fatal Accident Reporting data to assess the effect of teenage passengers on fatal crash rates.	<ul style="list-style-type: none"> • Simons-Morton • Albert (BBB) • Z. Zhang (BBB)

Project Title	Research Goal	Investigators
Teen Passenger Effects on Simulated Driving	Evaluate teenagers driving a simulator with passengers who are study confederates to determine the effects of various passenger-driver characteristics on driving performance.	Simons-Morton

Table 6B: Young Driver Intervention Studies

Project Title	Research Goal	Investigators
Rhode Island Young Driver Intervention (Checkpoints) Trial	Determine the effect in a randomized trial of the Checkpoints Program, administered at motor vehicle administration offices at permit and licensure.	<ul style="list-style-type: none"> • Simons-Morton • Wang
Connecticut Driver Education Online Checkpoints with Chat Room Trial	Determine the effect in a randomized trial of the Checkpoints Program conducted in driver education with an online program and chat room.	<ul style="list-style-type: none"> • Simons-Morton • Wang
Michigan Checkpoints Translation Study	Evaluate the efficacy of the Checkpoints Program administered in driver education using a group-randomized trial.	<ul style="list-style-type: none"> • Simons-Morton • Wang
Michigan Checkpoints Dissemination Study	Evaluate the effects of the Checkpoints Program administered by driver education professionals in Michigan driver education programs (group-randomized trial).	<ul style="list-style-type: none"> • Simons-Morton • Wang
American Automobile Association (AAA) Checkpoints Translation Study	Evaluate the effects of the online AAA Checkpoints Program on parent limit setting on young drivers at licensure.	Simons-Morton

Table 6C: Adolescent Behavior Studies

Project Title	Research Goal	Investigators
Health Behavior in School Children (HBSC) Survey	Assess the prevalence of health behaviors and identify factors associated with them in a national probability sample of sixth- to tenth-grade students, allowing for trend analyses and cross-national comparisons among the more than 40 countries involved in the quadrennial international HBSC surveys.	<ul style="list-style-type: none"> • Iannotti • Simons-Morton • Rovner (IRTA Fellow) • Nansel • Farhat (IRTA Fellow) • Haynie • Wang • Albert (BBB) • Z. Zhang (BBB)
NEXT Longitudinal Survey of Adolescent Health Behavior	Identify the trajectory of adolescent health status and health behaviors from mid-adolescence through the post high-school year; examine individual predictors of the onset of key adolescent risk behaviors and risk indicators during this period.	<ul style="list-style-type: none"> • Iannotti • Simons-Morton • Farhat (IRTA Fellow) • Wang • Rovner (IRTA Fellow) • Haynie

Table 6D: Studies on the Management of Childhood Diabetes

Project Title	Research Goal	Investigators
Family Management of Childhood Diabetes Trial	Determine whether a clinic-integrated, low-intensity, multicomponent behavioral intervention is effective in preventing the deterioration in glycemic control, treatment adherence, and quality-of-life that commonly occur during late childhood and early adolescence in youth with Type 1 diabetes.	<ul style="list-style-type: none"> • Nansel • Iannotti • Haynie • Albert (BBB) • Z. Zhang (BBB)
Developmental Influences on Management of Type 1 Diabetes	Examine the influence of family, social, and behavioral variables on diabetes self-management behaviors with a particular focus on adolescent developmental transitions.	<ul style="list-style-type: none"> • Iannotti • Nansel • Haynie • Simons-Morton
Diabetes Personal Trainer Study	Test the efficacy of an individualized, problem-solving intervention delivered by specially trained lay staff.	<ul style="list-style-type: none"> • Nansel • Iannotti • Simons-Morton • Rovner (IRTA Fellow)
Transition from Pediatric to Adult Diabetes Care	Examine Type 1 diabetes self-management and psychosocial concomitants before, during, and after the transition from pediatric to adult care; evaluate transition clinic models.	Iannotti
Enhancing Carbohydrate Quality in Diabetes Management Trial	Test a family-based behavioral intervention designed to promote consumption of carbohydrates from nutrient-dense, low-glycemic whole foods; determine the efficacy of such a dietary change in promoting improved health outcomes among children and adolescents with Type 1 diabetes.	<ul style="list-style-type: none"> • Nansel • Rovner (IRTA Fellow) • Haynie • Albert (BBB) • Zhang (BBB)
Dietary Intake in Pediatric Type 1 Diabetes	Examine the influence of social and cognitive factors on dietary intake among children with Type 1 diabetes and the relationship of dietary behavior with diabetes management.	<ul style="list-style-type: none"> • Nansel • Rovner (IRTA Fellow) • Haynie
Blood Glucose Response to Meals of Varying Glycemic Index	Test blood-glucose response to low and high glycemic-index meals using continuous glucose monitoring in both a controlled clinic setting and at home <i>ad libitum</i> .	<ul style="list-style-type: none"> • Nansel • Rovner (IRTA Fellow)
Feasibility and Acceptability of a Low Glycemic Index Diet in Diabetes Camp	Examine feasibility and acceptability of dietary change among youth with Type 1 diabetes.	<ul style="list-style-type: none"> • Nansel • Rovner (IRTA Fellow)

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APPENDIX A: BIOSKETCHES OF DIVISION PERSONNEL

OFFICE OF THE DIRECTOR

Germaine M. Buck Louis, Ph.D., M.S., was named Division director in November 2009, after serving as Acting director since August 2007; she is also chief and a senior investigator in the Division's Epidemiology Branch. Prior to joining the NICHD, Dr. Louis was a professor for 13 years in the Department of Social and Preventive Medicine, School of Medicine and Biomedical Sciences, at the University of Buffalo, where she developed original research focusing on the reproductive and/or developmental toxicity of persistent environmental chemicals in the context of behavior, now under study in the Longitudinal Investigation of Fertility and Environment and Endometriosis: Natural History, Diagnosis and Outcomes Studies. Dr. Louis has been an active member of several epidemiologic societies, including service as secretary, then president of the Society of Perinatal and Pediatric Epidemiologic Research (SPER) and as former board member of the American College of Epidemiology and the International Society of Environmental Epidemiology. She has served on a number of committees, panels, and boards for The National Academies, the U.S. Environmental Protection Agency, Pan American Health Organization, World Health Organization (WHO), and Assisted Human Reproduction Canada.

Maurice Davis, M.P.A., M.H.S.A., is a health scientist administrator in the Division's Office of the Director. Mr. Davis received his masters' in public administration/health services administration degrees from Grambling State University. He joined the NICHD in 2002 and serves as project coordinator for the NIH-D.C. Initiative to Reduce Infant Mortality in Minority Populations Research Network. His research interests include health disparities issues, especially infant mortality, affecting minority populations and minority children's perceptions of health research careers.

Michele Kiely, Dr.P.H., M.P.H., is a perinatal and pediatric epidemiologist who joined the Division in 2002 to run the congressionally mandated NIH-D.C. Initiative to Reduce Infant Mortality in Minority Populations. Her research interests include how events during pregnancy impact infant and child development, health disparities, and prevention of infant mortality. Currently, Dr. Kiely oversees the Reduction of Tobacco Exposure in Pregnancy and Infancy Study, which utilizes a behavioral intervention and nicotine replacement therapy to help women not smoke during pregnancy; and GirlTalk for Teen Moms, a study attempting to delay second pregnancies among teen moms. From 2005 to 2008, she was one of the American editors for *Paediatric and Perinatal Epidemiology*. Dr. Kiely represented the NICHD as the senior visiting scientist in the Office of the Surgeon General, between 2005 and 2008. She often represents the Institute at meetings with the D.C. Department of Health, including the implementation of its City-wide Action Plan to reduce infant mortality, and participates in the D.C. Advisory Committee on Perinatal, Infant, and Inter-conceptional Health and Development.

Patricia Moyer B.S., B.A., is a computer and information technology (IT) specialist in the Computer Sciences Section, having joined the Division in 1991. In this role, Ms. Moyer provides statistical programming support for Division members with expertise in various

computing languages for a variety of platforms. She also provides assistance to the Division using state-of-the-art solutions to resolve problems.

Ann Trumble, Ph.D., is chief of the Computer Science Section and has been with the Division since 1992. Dr. Trumble is a member of the Division's senior leadership and is responsible for organizing computer support for Division scientists and visiting researchers. Dr. Trumble serves as an analyst for several Division projects and is the Contract Officer Technical Representative for two Division-wide support contracts: one for onsite programming and statistical support, and the other for the biospecimen repository, which supports several components within NICHD.

BIostatistics & Bioinformatics Branch

Paul S. Albert, Ph.D., joined the Branch as chief and senior investigator in July 2009. He has more than 20 years of experience at NIH, with extensive experience in methodological and collaborative research. His methodological research is in the areas of longitudinal data analysis, methods for diagnostic medicine, and the analysis of biomarker data. He is a Fellow of the American Statistical Association and an associate editor for *Statistics in Medicine*.

Zhen Chen, Ph.D., joined the Branch in July 2009 as an investigator, after being in the Epidemiology Branch since 2008. He received his Ph.D. in statistics from the University of Connecticut in 2001. After graduation, he spent two years at the National Institute of Environmental Health Sciences in Research Triangle Park, North Carolina, as a research fellow in the Biostatistics Branch. Prior joining the NICHD in 2008, Dr. Chen was an assistant professor in the Department of Biostatistics and Epidemiology at the University of Pennsylvania. Dr. Chen's current methodological research interests include Bayesian data analysis, informative cluster size, and random effects selections. He is also collaborating with investigators within NICHD on various studies, including time to pregnancy and endometriosis diagnosis.

Sung Duk Kim, Ph.D., is a research fellow who joined the Branch in October 2007. He received his Ph.D. from the Pusan National University, Busan, South Korea, in 2004. Before joining the NICHD, he was a postdoctoral fellow at the University of Connecticut, Storrs, from 2004 to 2007. His research interests include Bayesian statistical methodology, statistical modeling for human fecundity, categorical data analysis, missing data analysis, and survival data analysis.

Aiyi Liu, Ph.D., is a senior investigator who received his doctorate degree from the University of Rochester in 1997. His research interests include: statistical methods for biomarkers, focusing on issues such as diagnostic accuracy and receiver-operating characteristic (ROC) curves analysis, limit of detection, and measurement error; sequential and adaptive methodology and applications to biomedical research; and semiparametric and nonparametric methods for multiple outcomes.

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Rajeshwari Sundaram, Ph.D., is an investigator who joined the Branch in 2006. Dr. Sundaram received her master's degree in statistics from Indian Statistical Institute, Kolkata, India, and her doctorate in statistics from Michigan State University in 1999. After graduation, she joined mathematics department at the University of North Carolina, Charlotte, where she was an assistant professor from 1999 to 2006. Her research interests include survival analysis, joint modeling of longitudinal and time-to-event data with applications to fecundity, and other issues in reproductive epidemiology.

James F. Troendle, Ph.D., is a senior investigator who has been a member of the Branch since 1992. He earned his Ph.D. from the University of Maryland, College Park. His research interests include multiple hypothesis testing, nonparametric tests, and methodology for genetic association tests.

Kai Fun Yu, Ph.D., is a senior investigator who received his doctorate degree from Columbia University. Dr. Yu has broad interests in the theory, methodology, and applications of statistics and probability. He has worked in many areas, including sequential analysis, longitudinal data analysis, categorical data analysis, neural network, clustering and classification, nonparametric statistics, and adaptive sampling. Recent emphases include sequential clinical trials, longitudinal data analysis, and nonparametric procedures.

Zhiwei Zhang, Ph.D., joined the Branch in September 2009 as an investigator. He received his Ph.D. in biostatistics from the University of Pittsburgh in 2003. He worked for the Food and Drug Administration for four years before joining the NICHD. Dr. Zhang has conducted research in the areas of missing data, clinical trials, and causal inference. Most recently, his research focus has been in the area of longitudinal data analysis.

EPIDEMIOLOGY BRANCH

Dr. Mary L. Hediger, Ph.D., is a biological anthropologist who joined the Branch in 1997 to work on projects relating to human growth and development. Currently, Dr. Hediger is the acting chief of the Epidemiology Branch. Her research interests include fetal, child, and adolescent growth and development; perinatal epidemiology; and growth and nutrition. Dr. Hediger leads the Upstate New York Infant Development Screening Study to determine the relation between infertility treatment and child growth and development through age three years. Since 2005, Dr. Hediger has represented the Branch and the NICHD on a number of working groups and panels. She served as a panelist at the Workshop on the Epidemiology of Communication Disorders for the National Institute on Deafness and Other Communication Disorders (2005); the National Health and Nutrition Examination Survey Pubertal Maturation Workshop for Development of a Self-Assessment Component (2005); the National Research Council's Workshop on the Impact of Pregnancy Weight on Maternal and Child Health (2006); the Expert Review Panel on the Evaluation of the WHO Child Growth Standards and Centers for Disease Control and Prevention (CDC) Growth Charts (2006); and the Anthropometrics Working Group (2008-2009) for the National Human Genome Research Institute (NHGRI) PhenX project. Dr. Hediger has served on the Executive Committees of the Human Biology Association and SPER and was president of SPER (2006).

Mary Conley, M.A., joined the Branch in 1991 as an IT specialist. She received her A.B. from Emmanuel College, in Boston, and her master's from St. John's University, New York. She worked as a medical data analyst at the Albert Einstein College of Medicine of Yeshiva University and at the University of Alabama Medical Center at Birmingham before joining the Branch. Her research interests include the effects of prenatal exposure to alcohol and the biochemical and genetic causes of birth defects.

Jagteshwar (Una) Grewal, Ph.D., M.P.H., is a staff scientist who joined the Epidemiology Branch in September 2007. Since then, her primary perinatal and pediatric research interests have included fetal growth and development and birth defects. Dr. Grewal is an integral member of the research team of Dr. Jun (Jim) Zhang, a senior investigator in the Branch, and plays a key role in the implementation of his studies. She designed an original data collection component within the National Standard of Normal Fetal Growth Study, following successful competitive extramural funding from the NIH Office of Dietary Supplements, to determine nutrient and supplement intake among pregnant women in the United States. In addition, Dr. Grewal continues her research focusing on the etiologic determinants of birth defects, building upon her earlier experience with the California Birth Defects Monitoring Program.

Mark A. Klebanoff, M.D., M.P.H., is a senior investigator, with board certification in pediatrics, who joined the Branch in 1982. He served as Division director from 1998 until 2008, when he returned to the Branch. Dr. Klebanoff's work focuses on various aspects of pregnancy and child health, including genital tract infection as a cause of preterm birth, and the intergenerational correlation of pregnancy outcomes. He is a member of the Editorial Board of the *American Journal of Epidemiology*, the NIH Epidemiology-Statistics Tenure Advisory Committee, and the Award Selection Committee of the Coalition for Excellence in Maternal and Child Health Epidemiology. Dr. Klebanoff is an elected member of the Society for Pediatric Research, the American Epidemiological Society, and the Johns Hopkins Society of Scholars.

Richard Levine, M.D., M.S., M.P.H., is a senior investigator who joined the Branch in 1991. Dr. Levine's current research interests focus on the pathogenesis of preeclampsia, with particular emphasis on the role of angiogenic factors. Dr. Levine is the recipient of the NIH Director's Award (2005) and a Research Excellence Award from the Society for Maternal-Fetal Medicine (2006). He is also co-chair of the NIH Translational Research Interest Group and a member of the Trans-NIH Angiogenesis Research Program.

James L. Mills, M.D., M.S., is a senior investigator with postgraduate certification in pediatrics and pediatric endocrinology. He was a Robert Wood Johnson Clinical Scholar at the University of Pennsylvania, where he earned a master's degree in epidemiology. He is a member of the senior biomedical research service and has performed research on a range of pediatric and pregnancy problems, particularly birth defects. In recent years, much of his work has focused on biochemical and genetic factors in birth defects, particularly neural tube defects. He is expanding his research to encompass other birth defects, including oral clefts, and is employing new large-scale genotyping approaches. He is also interested in the effects of food fortification with folic acid and the effects of prenatal alcohol exposure.

Neil Perkins, Ph.D., is a staff scientist who was recruited to the Branch in 2007. Dr. Perkins's research focuses on statistical and epidemiological methods for evaluating biomarkers in the presence of various types of measurement error. Specifically, he has developed several techniques for estimating the ROC curves and summary measures of the ROC correcting for common sources of outside uncertainty, including data affected by a limit of detection. He is a regular reviewer for high-impact major epidemiological and statistical journals and is an active member of both the American Statistical Association and the Society for Epidemiologic Research, presenting frequently at their respective conferences.

Enrique F. Schisterman, Ph.D., M.A., is a senior investigator who was recruited to the Branch in 2002 for his expertise in epidemiologic methods research, an area which impacts all Division research. Dr. Schisterman's research interest focuses on exposure assessment, with emphasis on the use of oxidative stress biomarkers, in relation to reproductive health, and on the development of analytic methods for assessing biomarkers and human health. Dr. Schisterman is professionally active and serves on the Editorial Boards for the *American Journal of Epidemiology* and *Epidemiology*, serves on various expert panels for the CDC and NIH, and annually organizes the methods course for SPER.

Cuilin Zhang, M.D., Ph.D., M.P.H., is a tenure-track investigator who joined the Epidemiology Branch in 2007. Dr. Zhang's work focuses on both the etiological and preventive aspects of gestational diabetes, Type 2 diabetes, and related metabolic and reproductive disorders. Dr. Zhang is actively involved in professional service to NIH and other external bodies. She is a regular reviewer for high-impact major epidemiological and medical journals, a member of the Editorial Board and the academic editor for the *Public Library of Science ONE*, and a grant reviewer for Michigan Diabetes Research and Training Center. She is a regular presenter at national and international meetings and served as the CDC's expert panelist for Gestational Diabetes: Beyond Pregnancy Conference in 2007. In addition, Dr. Zhang is a member of the NICHD Obesity Research Strategic Core and serves as the NICHD representative for NIH Roadmap Genotype/Tissue Expression Working Group.

Jun (Jim) Zhang, M.D., Ph.D., M.P.H., was recruited in 1997, was tenured by the NIH in 2005, and since that time has been a senior investigator in the Epidemiology Branch. He has a broad interest in obstetric and perinatal research, which has important implications in obstetric practice, such as labor and delivery, normal and abnormal fetal growth, and preeclampsia. Dr. Zhang has also devoted a substantial amount of time to training Intramural Research Training Award fellows and summer interns and has served on various committees inside and outside NIH. He served on the Data and Safety Monitoring Committee for the NICHD Reproductive Medicine Network and is currently an Advisory Board member for the Institute's Neonatal Research Network and a member of the Reproductive Health Measures Working Group in the NHGRI PhenX Project. He has also served on NIH and international scientific review committees. He has been an associate editor for the *American Journal of Epidemiology* and a regular reviewer for 10 other journals.

PREVENTION RESEARCH BRANCH

Bruce Simons-Morton, Ed.D., M.P.H., became the PRB Branch chief in 1997, after being a senior investigator since 1992. He completed his doctorate in health education at the University of Northern Colorado in 1976 and received his M.P.H. from Johns Hopkins University School of Public Health in 1980. He was an assistant professor of health education at Temple University until 1980. In 1983, he became associate professor at the University of Texas Medical Branch in Galveston, Texas, was tenured in 1988, and then moved to the School of Public Health, University of Texas Health Science Center at Houston in 1989, where he was tenured in 1991. His research focuses on the determinants of adolescent health behavior and the evaluation of behavioral interventions within two areas: adolescent health behavior and young drivers.

Denise L. Haynie, Ph.D., M.P.H., was brought into the Branch as a postdoctoral fellow in 1993, was promoted to research fellow in 1998, and became a staff scientist in 2000. Prior to 1993, she was a research associate at the Department of Community Health, Georgetown Medical School. She completed a doctorate in developmental psychology at the Catholic University of America in 1993, and then received a master's of public health from the Johns Hopkins University School of Public Health in 1996. Her research interests include school-based intervention and prevention research, with a focus on problem behavior and youth development. More recently, she has worked on research examining the effects of promoting consumption of nutrient-dense whole foods on management of Type 1 diabetes among early adolescents.

Ronald J. Iannotti, Ph.D., was appointed a senior staff fellow in 2001 and became a staff scientist in 2005. He holds a doctorate in developmental psychology from the State University of New York, Buffalo, and a master's in experimental psychology from Hollins College. He was an associate professor at Marietta College from 1980 to 1985; he then moved to the Georgetown University School of Medicine Department of Community and Family Medicine, where he was a research associate professor, and was associate director of the Division of Children's Health Promotion from 1985 to 1993. In 1993, he accepted a position at the Miami University, Ohio, as associate professor and was tenured as a full professor in 1997. His research interests include social and environmental influences on the development of children's health behaviors, including obesity, medicine use, bullying, body image, physical activity, sedentary behavior, and diet. He also has interest in improving management of chronic illnesses in children.

Tonja Nansel, Ph.D., was hired as a postdoctoral fellow in 1998 and was promoted to tenure-track investigator in 2001. She obtained a doctorate in community/clinical psychology from Wichita State University in 1998. Her primary research interests include chronic disease prevention and management, particularly diabetes, and the integration of prevention and health promotion in the health care setting. Her most recent research examines the impact of improving dietary consumption, including more nutrient-dense whole foods, on the management of Type 1 diabetes.

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Jing Wang, Ph.D., was hired as a postdoctoral fellow in 2007 and was promoted to research fellow in 2009. In 2007, she received her doctorate in quantitative psychology from Bowling Green State University and holds master of arts and master of science degrees in experimental psychology and health promotion, respectively, from Morehead State University. Her research focuses on the integration of advanced quantitative methods (e.g., structural equation, multilevel, and item-response modeling) to the examination of psychological, social, and developmental processes, particularly within the study of prevention research.

OTHER PERSONNEL

Since the Division's last report to Council, the following staff have left the Division (date of departure, new position):

- Dr. Ruth Brenner (2006, National Children's Study)
- Dr. Feng-Ying Lin (2006, NICHD Division of Intramural Research)
- Dr. Gitanjali Taneja (2006, Westat)
- Dr. Ondine von Ehrenstein (2007, University of California, Los Angeles)
- Dr. Courtney Lynch (2008, Ohio State University College of Public Health)

**APPENDIX B: DIVISION FELLOWS, INTERNS, AND TRAINEES,
FISCAL YEAR 2005 THROUGH FISCAL YEAR 2009**

INTRAMURAL RESEARCH TRAINING AWARD (IRTA) FELLOWS AND INTERNS, OFFICE OF THE DIRECTOR

Name	Prior Institution	NICHD Mentor	NICHD Position	Dates	Current Institution
Rebecca Brotman, M.P.H.	Johns Hopkins University	Klebanoff	Predoctoral IRTA Fellow	2005-2007	University of Maryland School of Medicine
Anusha Hemachandra-Strebel, M.D., M.P.H.	Johns Hopkins University	Klebanoff	IRTA Fellow	2004-2007	University of Colorado
Quinton Swain	St. Mary's College	Davis	Intern	2005	
Michele Yeboah, Dr.P.H.	Morgan State University	Davis	Presidential Management Fellow	2005-2006	U.S. Department of Health and Human Services

IRTA FELLOWS, BIOSTATISTICS & BIOINFORMATICS BRANCH

Name	Prior Institution	NICHD Mentor(s)	NICHD Position	Dates	Current Institution
Michelle Dunaher, B.A.	University of Maryland, Baltimore County	Albert (co-mentor)	Predoctoral IRTA Fellow (Epidemiology Branch [EB])	2009	
Seunggeun Hyun, M.S.	University of North Carolina, Charlotte	Sundaram	Visiting Predoctoral Fellow	2006-2007	University of South Carolina
Sung Duk Kim, Ph.D.	University of Connecticut	Sundaram	Visiting Fellow	2007-2008	NICHD
Chunling Liu, Ph.D.	University of Hong Kong	Liu	Visiting Fellow	2008	
Kirsten Lum, M.S.	American University	Sundaram	Predoctoral Fellow	2008-2009	Johns Hopkins University
Yaakov Malinovsky, Ph.D.	Hebrew University	Albert (co-mentor)	Visiting Fellow (EB)	2009	
Alexander McLain, Ph.D.	North Carolina State University	Sundaram	Visiting Fellow	2009	

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Name	Prior Institution	NICHD Mentor(s)	NICHD Position	Dates	Current Institution
Kantahyane Murray, M.S.	University of Maryland	Sundaram (co-mentor)	Predoctoral Fellow, (Prevention Research Branch)	2006-2007	Johns Hopkins School of Medicine
Albert Vexler, Ph.D.	Hebrew University	Liu	Visiting Fellow	2004-2007	State University of New York at Buffalo
Chengqing Wu, Ph.D.	University of Science and Technology of China	Liu	Visiting Fellow	2003-2007	Yale University
Mixia Wu, Ph.D.	Beijing University of Technology	Yu	Visiting Fellow	2006-2008	Beijing University of Technology
Bo Zhang, Ph.D.	University of Minnesota	Chen and Albert	Visiting Fellow	2009	

SUMMER INTERNS, BIostatISTICS AND BIOinformatics BRANCH

Name	Institution	Date	NICHD Mentor
Elizabeth Dahlquist	University of South Florida	2005	Liu
Angel Davalos	University of Maryland, Baltimore County	2009	Liu
Ekaterina Eliseeva	University of Chicago	2006	Liu (co-mentored with Vexler)
Xiaoshu Feng	University of Maryland, Baltimore County	2008	Liu
Helen Guo	University of Virginia	2007	Liu
Sandra Hurtado-Rua	University of Connecticut	2008	Sundaram
Kirsten Lum	American University	2007	Sundaram
Elaine Nsoesie	University of Maryland	2007	Sundaram
Elaine Nsoesie	Virginia Polytechnic Institute and State University	2009	Kim

NOTE: All summer interns participated in the NIH Research Poster Day for summer interns.

IRTA FELLOWS, EPIDEMIOLOGY BRANCH

Name	Prior Institution	NICHD Mentor(s)	NICHD Position	Dates	Current Institution
Anastasia Blink	London School of Hygiene	Levine	Predoctoral IRTA Fellow	2004-2005	
Michael Bloom, Ph.D., M.S.	State University of New York (SUNY), Buffalo	Schisterman	Postdoctoral IRTA Fellow	2004-2006	University of Albany School of Public Health
Katherine Bowers	Johns Hopkins University	C. Zhang	Postdoctoral IRTA Fellow	2009	
Rebecca Brotman, Ph.D.	Johns Hopkins University	Klebanoff	Predoctoral IRTA Fellow	2005-2007	University of Maryland
Tonia Carter, Ph.D., M.S.	SUNY Albany	Mills	Visiting Fellow	2007	
Liwei Chen, M.D., Ph.D.	Johns Hopkins University	C. Zhang	Visiting Fellow	2008-2009	Louisiana State University
Maureen Cooney, M.P.H.	University of North Carolina	Buck Louis	Predoctoral IRTA Fellow Postdoctoral IRTA Fellow	2005-2009 2009	
Michelle Danaher, B.A.	University of Maryland, Baltimore County	Schisterman (Co-mentor)	Predoctoral IRTA Fellow (Funded by the American Chemistry Council [ACC])	2009	
Anca Dragomir, Ph.D.	University of North Carolina	Buck Louis	Postdoctoral IRTA Fellow	2007-2009	
Jessie Ford, B.A.	Brown University	J. Zhang	Postbaccalaureate IRTA Fellow	2007-2008	Laos, Vietnam
Audrey Gaskins, B.S.E.	Duke University	Schisterman	Postbaccalaureate IRTA Fellow (ACC Funded)	2008	
Audra Gollenberg, Ph.D.	University of Massachusetts	Hediger	Postdoctoral IRTA Fellow	2008	
Alexis Handal, Ph.D., M.P.H.	University of Michigan	Buck Louis	Postdoctoral IRTA Fellow	2006-2007	University of New Mexico
Penelope Howards, Ph.D.	University of North Carolina	Schisterman	Postdoctoral IRTA Fellow	2004-2007	Emory University School of Public Health
Leila Jackson, Ph.D., M.P.H.	Johns Hopkins University	Louis and Schisterman	Postdoctoral IRTA Fellow	2003-2005	Case Western Reserve University School of Medicine

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Name	Prior Institution	NICHD Mentor(s)	NICHD Position	Dates	Current Institution
Sarah Laughon, M.D., M.S.	University of Pittsburgh	J. Zhang	Postdoctoral IRTA Fellow	2009	
Yaakov Malinovsky, Ph.D.	Hebrew University	Schisterman (Co-mentor)	Predoctoral IRTA Fellow (ACC Funded)	2009	
Rafael Mikolajczyk, M.D., M.S.P.H.	University of Bielefeld, Germany	J. Zhang	Visiting Fellow	2007-2008	University of Bielefeld, School of Public Health
Sunni Mumford, M.S.	University of North Carolina	Schisterman	Predoctoral IRTA Fellow	2008	
Gila Neta, Ph.D.	Johns Hopkins University	J. Zhang	Predoctoral IRTA Fellow	2008-2009	National Cancer Institute
Geeta Patel, B.A.	University of Texas, Austin	J. Zhang	Postbaccalaureate IRTA Fellow	2004-2005	SUNY Long Island
Neil Perkins, M.S., Ph.D.	American University	Schisterman	Predoctoral IRTA Fellow Postdoctoral IRTA Fellow	2004-2007 2007-2008	Epidemiology Branch, Division of Epidemiology, Statistics, and Prevention Research, NICHD
Anna Pollack, B.A., M.P.H.	Johns Hopkins University	Schisterman	Predoctoral IRTA Fellow (ACC Funded)	2009	
Leslie Rosenthal, B.A.	Emory University	Schisterman	Postbaccalaureate IRTA Fellow	2007-2008	University of Iowa School of Medicine
Marcus Roupp, B.A.	Yale University	Schisterman	Postbaccalaureate IRTA Fellow	2006-2007	University of Massachusetts School of Medicine
Caroline Signore, M.D., M.P.H.	George Washington University	Mills	Postdoctoral IRTA Fellow	2004-2007	Pregnancy and Perinatology Branch, Center for Developmental Biology and Perinatal Medicine, NICHD
Sarah Stark, B.S.	Bucknell University	J. Zhang	Postbaccalaureate IRTA Fellow	2003-2004	Johns Hopkins University
Anusha H. Streubel, M.D., M.P.H.	Johns Hopkins University	Klebanoff	Postdoctoral IRTA Fellow	2004-2007	University of Colorado
Marie Thoma, M.P.H.	Johns Hopkins University	Klebanoff	Predoctoral IRTA Fellow	2009	

The information in this document is no longer current. It is intended for reference only.

Name	Prior Institution	NICHD Mentor(s)	NICHD Position	Dates	Current Institution
Brian Whitcomb, Ph.D.	University of Maryland, Baltimore	Schisterman	Predoctoral IRTA Fellow	2004-2007	University of Massachusetts School of Public Health
			Postdoctoral IRTA Fellow	2007-2008	Johns Hopkins University
Edwina Yeung, Ph.D.	Johns Hopkins University	C. Zhang and Schisterman	Postdoctoral IRTA Fellow	2008	
Qian Zhang, B.S.	University of Chicago	Schisterman	Postbaccalaureate IRTA Fellow	2009	

MILITARY FELLOWS, EPIDEMIOLOGY BRANCH

Name	Prior Institution	NICHD Mentor	NICHD Position	Dates	Current Institution
Elizabeth Flanigan, M.D., M.P.H.	Uniformed Services University	Mills	Neonatology Fellow	2007-2009	U.S. Army
Alexander Holston, M.D.	Uniformed Services University	Levine	Neonatology Fellow	2007-2009	
Devon Kuehn, M.D.	Uniformed Services University	Mills	Neonatology Fellow	2009	

SUMMER INTERNS, EPIDEMIOLOGY BRANCH

Name	Institution	Date	NICHD Mentor(s)
Deirdre Banel	Harvard University School of Public Health	2009	C. Zhang
Sara Bodach*	Yale University School of Medicine	2007	Perkins and Whitcomb
Emily Bucholz	Yale University School of Public Health	2008	Hediger
Alexis DiSilvestro*	Pennsylvania State University School of Medicine	2007	J. Zhang
Audra Gollenberg*	University Massachusetts, Amherst	2006	Lynch
Chunyan He	Harvard University School of Public Health	2008	C. Zhang
Courtney Hilts*	Drexal University School of Public Health	2009	J. Zhang
Anandhi Jeyabalan*	University of Michigan School of Public Health	2005	Levine
Homa Khorrami	George Washington University School of Medicine	2005	Mills
Rebecca LePrelle*	Emory University School of Public Health	2006	Saluja
Mark Masciocchi*	Pennsylvania State University School of Medicine	2007	J. Zhang

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Name	Institution	Date	NICHD Mentor(s)
Sunni Mumford*	Harvard University School of Public Health	2005	Schisterman
Sunni Mumford*	University of North Carolina School of Public Health	2006	Schisterman
Sunni Mumford*	University of North Carolina School of Public Health	2007	Schisterman
Gila Neta*	Johns Hopkins University School of Public Health	2008	von Ehrenstein
Melissa Park*	University of North Carolina School of Public Health	2005	Zhang
Josefa Peña*	Texas A&M University, Rural School of Public Health	2006	Buck Louis and Hediger
Anna Pollack*	George Washington University School of Public Health	2007	Lynch
Anna Pollack*	Johns Hopkins University School of Public Health	2008	Buck Louis
Jeremy Rassen*	Harvard University School of Public Health	2005	Lynch and Buck Louis
Candace Robledo*	Texas A&M University, Rural School of Public Health	2006	J. Zhang
Karen Schliep*	University of Utah	2009	Schisterman
Parth Shah	Texas A&M University, Rural School of Public Health	2006	J. Zhang
Aisha Siebert*	Columbia University School of Public Health	2007	Buck Louis and Lynch
Rebecca Stevens*	Walt Whitman High School	2006	Buck Louis and Lynch
Kira Taylor*	Emory University School of Public Health	2005	Buck Louis
Jillian Tsai*	Vanderbilt University School of Medicine	2006	Levine
Meghan Wernicke	Texas A&M University, Rural School of Public Health	2008	Grewal
Irene Woo*	Pennsylvania State University School of Medicine	2007	Mills, Conley and Flanigan
Emily Zabor*	University of Minnesota School of Public Health	2009	Klebanoff

NOTE: *Denotes participation in the NIH Research Poster Day for Summer Interns.

IRTA FELLOWS, PREVENTION RESEARCH BRANCH

Name	Prior Institution	NICHD Mentor	NICHD Position	Dates	Current Institution
Maria Botello-Harbaum, Ed.D.	Columbia University	Haynie	Postdoctoral IRTA Fellow	2005-2008	The EMMES Corporation
Laura Caccavale, B.A.	Wake Forest University	Haynie	Postbaccalaureate IRTA Fellow	2009	
Kimberly Chambers, B.A.	University of Delaware	Haynie	Postbaccalaureate IRTA Fellow	2006-2007	George Mason University
Caitlin Duffy	Cornell University	Haynie	Postbaccalaureate IRTA Fellow	2008-2009	Northwestern University
Kathleen Engeln, B.A., B.S.	University of Washington	Haynie	NIH Undergraduate Scholar Program	2009	
Tilda Farhat, Ph.D.	University of North Carolina School of Public Health	Simons-Morton	Postdoctoral IRTA Fellow	2007	
Lauren Gase, B.S.	University of California	Haynie	Postbaccalaureate IRTA Fellow	2005-2006	Emory University School of Public Health
Lauren Gellar, M.S.	Long Island University	Haynie	Postbaccalaureate IRTA Fellow	2003-2005	Columbia University/ University of Massachusetts Medical School
Jeremy Luk	University of Washington	Haynie	Postbaccalaureate IRTA Fellow	2008-2009	University of Washington
Amanda McEnery, B.A.	University of Notre Dame	Haynie	Postbaccalaureate IRTA Fellow	2006-2007	University of Indiana, Bloomington
Shermayne Moore, B.S.	Howard University	Haynie	Postbaccalaureate IRTA Fellow	2005-2006	Pennsylvania State University
Kantahyanee Murray, Ph.D.	University of Maryland	Haynie	Predoctoral IRTA Fellow	2004-2007	Johns Hopkins University School of Medicine
Elizabeth Noelcke, B.S.	University of North Carolina	Haynie	Postbaccalaureate IRTA Fellow	2006-2008	Center for Health Transformation
Erik Olsen, Ph.D.	Virginia Polytechnic Institute	Simons-Morton	Postdoctoral IRTA Fellow	2004-2008	Municipality of Blacksburg
Marie-Claude Ouimet, Ph.D.	University of Montréal	Simons-Morton	Visiting Fellow	2005-2009	University. of Sherbrooke, Quebec, Canada
Anuj Pradhan, Ph.D.	University of Massachusetts	Simons-Morton	Visiting Fellow	2009	

The information in this document is no longer current. It is intended for reference only.

Name	Prior Institution	NICHD Mentor	NICHD Position	Dates	Current Institution
Lisa Ramirez, B.A.	University of Texas	Haynie	Postbaccalaureate IRTA Fellow	2004-2005	Case Western Reserve University
Jessica Rath, Ph.D., M.P.H.	Johns Hopkins University, Bloomberg School of Public Health	Haynie	Predoctoral IRTA Fellow Postdoctoral IRTA Fellow	2003-2005 2005	University of Maryland Center for Health Behavior Research
Alisha Rovner, Ph.D.	Johns Hopkins University, Bloomberg School of Public Health	Nansel	Postdoctoral IRTA Fellow	2006	
Elizabeth Robinson, B.A.	University of Washington and Lee	Haynie	Postbaccalaureate IRTA Fellow	2007-2009	Virginia Commonwealth University
Madiha Tahseen, B.S.	University of Maryland	Haynie	Postbaccalaureate IRTA Fellow	2005-2006	University of Maryland, Baltimore County
Vijaya Thomas, B.S.	Brown University	Haynie	Postbaccalaureate IRTA Fellow	2007-2008	Boston University School of Medicine
Julia Tse, B.A.	Dartmouth College	Haynie	Postbaccalaureate IRTA Fellow	2009	
Jing Wang, Ph.D.	Bowling Green State University	Simons-Morton	Visiting Fellow	2007-2009	Fellow, Prevention Research Branch
Katherine Willson, B.A.	College of William and Mary	Haynie	Postbaccalaureate IRTA Fellow	2009	

SUMMER INTERNS, PREVENTION RESEARCH BRANCH

Name	Institution	Date	NICHD Mentor
Angel Barber	Howard University	2005	Haynie
Chakema Carmach	Wichita State University	2006	Nansel
Kathleen Engeln	University of Washington	2009	Haynie
Michael Flock	University of Dayton	2009	Haynie
Lauren Gellar	Columbia University	2005	Nansel
Lauren Gellar	Columbia University	2006	Nansel
Dana Litt	George Washington University	2007	Iannotti
Adrienne McGill	Johns Hopkins University	2006	Nansel
Aubrey Spriggs	University of North Carolina	2006	Iannotti
Molly Turnquist	Concordia College	2009	Haynie
Felicia Washington	Southern Illinois University School of Medicine	2005	Haynie

NOTE: All interns participated in the NIH Research Poster Day for summer interns.

APPENDIX C: DIVISION PUBLICATIONS, 2005 THROUGH 2009

(* denotes mentee first-authored publication; staff names appear in **bold**)

OFFICE OF THE DIRECTOR

2006

Siegel, R.M., Bien, J., Lichtenstein, P., Davis, J., Khoury, J.C., Knight, J.E., **Kiely, M.**, & Bernier, J. (2006). A safety-net antibiotic prescription for otitis media: The effects of a Practice-Based Research Network (PBRN) study on patients and practitioners. *Clinical Pediatrics (Phila)*, 45, 518-524.

2007

Blake, S.M., **Kiely, M.**, Gard, C.C., El-Mohandes, A.A., & El-Khorazaty, M.N. (2007). Pregnancy intentions and happiness among pregnant black women at high risk for adverse infant health outcomes. *Perspectives on Sexual and Reproductive Health*, 39, 194-205.

El-Khorazaty, M.N., Johnson, A.A., **Kiely, M.**, El-Mohandes, A.A., Subramanian, S., Laryea, H.A., Murray, K.B., Thornberry, J.S., & Joseph, J.G. (2007). Recruitment and retention of low-income minority women in a behavioral intervention to reduce smoking, depression, and intimate partner violence during pregnancy. *BMC Public Health*, 7, 233-251.

Murray, K.D., El-Mohandes, A.A., El-Khorazaty, M.N., & **Kiely, M.** (2007). Low-income minority mothers' reports of infant health care utilization compared with medical records. *Paediatric and Perinatal Epidemiology*, 21, 274-283.

2008

El-Mohandes, A.A., **Kiely, M.**, Joseph, J.G., Subramanian, S., Johnson, A.A., Blake, S.M., Gantz, M.G., & El-Khorazaty, M.N. (2008). An intervention to improve postpartum outcomes in African American mothers: A randomized controlled trial. *Obstetrics and Gynecology*, 112, 611-620.

Kiely, M. (2008). Prevention of preterm birth: A challenge not yet met. *U.S. Obstetrics and Gynecology*, 3(2), 48-50.

2009

Blake, S.M., Murray, K.D., El-Khorazaty, M.N., Gantz, M.G., **Kiely, M.**, Best, D., Joseph, J.G., & El-Mohandes, A.A. (2009). Environmental tobacco smoke avoidance among pregnant African American nonsmokers. *American Journal of Preventive Medicine*, 36, 225-234.

El-Mohandes, A.A., **Kiely, M.**, Gantz, M.G., Blake, S.M., & El-Khorazaty, M.N. (2009). Prediction of birth weight by cotinine levels during pregnancy in a population of black smokers. *Pediatrics*, 124, e671-e680.

Joseph, J.G., El-Mohandes, A.A., **Kiely, M.**, El-Khorazaty, M.N., Gantz, M.G., Johnson, A.A., Katz, K.S., Blake, S.M., Rossi, M.W., & Subramanian, S. (2009). Reducing psychosocial and

behavioral pregnancy risk factors: Results of a randomized clinical trial among high-risk pregnant African American women. *American Journal of Public Health*, 99, 1053-1061.

In Press

El-Mohandes, A.A., **Kiely, M.**, Blake, S.M., Gantz, M.G., & El-Khorazaty, M.N. (in press). A behavioral intervention reduces environmental tobacco smoke exposure (ETSE) during pregnancy and improves outcomes in African American women. *Pediatrics*.

Koo, H., Allison, R., El-Khorazaty, N., Yao, Q., Jenkins, R., Anderson, K., Walker, L., & **Davis, M.** (in press). Evaluation of a randomized intervention to delay sexual initiation among fifth graders followed through the sixth grade. *Sex Education, Sexuality, Society, and Learning*.

BIostatistics & Bioinformatics Branch

2005

Beste, L.A., England, L.J., Schisterman, E.F., Qian, C., **Yu, K.F.**, & Levine, R.J. (2005). Pregnancy outcomes in smokers who develop preeclampsia. *Paediatric & Perinatal Epidemiology*, 19, 12-18.

Emery, S.P., Levine, R.J., Qian, C., Ewell, M.G., England, L.J., **Yu, K.F.**, & Catalano, P.M. for the Calcium for Preeclampsia Prevention (CPEP) Study Group. (2005). Twenty-four-hour urine insulin as a measure of hyperinsulinaemia/insulin resistance before onset of preeclampsia and gestational hypertension. *BJOG: An International Journal of Obstetrics and Gynaecology*, 112, 1479-1485.

Guo, H., & **Liu, A.** (2005). A simple and efficient bias-reduced estimator of response probability following a group sequential phase II trial. *Journal of Biopharmaceutical Statistics*, 15, 773-781.

Letocha, A.D., Cintas, H.L., **Troendle, J.F.**, Reynolds, J.C., Cann, C.E., Chernoff, E.J., Hill, S.C., Gerber, L.H., & Marini, J.C. (2005). Controlled trial of pamidronate in children with types III and IV osteogenesis imperfecta confirms vertebral gains, but not short-term functional improvement. *Journal of Bone and Mineral Research*, 20, 977-986.

Levine, R.J., Thadhani, R., Qian, C., Lam, C., Lim, K.H., **Yu, K.F.**, Blink, A.L., Sachs, B.P., Epstein, F.H., Sibai, B.M., Sukhatme, V.P., & Karumanchi, S.A. (2005). Urinary placental growth factor and the risk of preeclampsia. *Journal of American Medical Association*, 293, 77-85.

Liu, A., Schisterman, E.F., & Wu, C.Q. (2005). Nonparametric estimation and hypothesis testing on the partial area under receiver-operating characteristic curves. *Communications in Statistics: Theory and Methods*, 34, 2077-2088.

Liu, A., Schisterman, E.F., & Zhu, Y. (2005). On linear combinations of biomarkers to improve diagnostic accuracy. *Statistics in Medicine*, 24, 37-47.

Liu, A., Schisterman, E.F., Mazumdar, M., & Hu, J. (2005). Power and sample-size calculation of comparative diagnostic accuracy studies with multiple correlated test results. *Biometrical Journal*, 47, 140-150.

- Liu, A.**, Wu, C.Q., **Yu, K.F.**, & Gehan, E. (2005). Supplementary analysis of probabilities at the termination of a group sequential phase II trial. *Statistics in Medicine*, *24*, 1009-1027.
- Nilsson, O., Mitchum, R.D., Schrier, L., Ferns, S.P., Barnes, K.M., **Troendle, J.F.**, & Baron, J. (2005). Growth plate senescence is associated with loss of DNA methylation. *Journal of Endocrinology*, *186*, 241-249.
- Poola, I., Fuqua, S.A.W., DeWitty, R.L., Abraham, J., Marshallack, J.J., & **Liu, A.** (2005). ER α -negative breast cancer tissues express significant level of ER β 1 and ER β 5: Potential molecular targets(s) for chemo-prevention. *Clinical Cancer Research*, *11*, 7579-7585.
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- Troendle, J.F.** (2005). Comments on: A bootstrap test of stochastic equality of two populations. *The American Statistician*, *59*, 279.
- Troendle, J.F.** (2005). Multiple comparisons between two groups on multiple Bernoulli outcomes while accounting for covariates. *Statistics in Medicine*, *24*, 3581-3591.
- Troendle, J.F.**, **Liu, A.**, Wu, C.Q., & **Yu, K.F.** (2005). Sequential testing for efficiency in clinical trials with non-transient effects. *Statistics in Medicine*, *24*, 3239-3250.
- Vahratian, A., Zhang, J., **Troendle, J.F.**, Sciscione, A.C., & Hoffman, M.K. (2005). Labor progression and risk of cesarean delivery in electively induced nulliparas. *Obstetrics and Gynecology*, *105*, 698-704.

2006

- Biswas, A., & **Sundaram, R.** (2006). Kernel survival function estimation based on doubly censored data. *Communications in Statistics: Theory and Methods*, *35*, 1293-1307.
- Datta, S., & **Sundaram, R.** (2006). Nonparametric marginal estimation in a multistage model using current status data. *Biometrics*, *62*, 829-837.
- Hoffman, M.K., Vahratian, A., Sciscione, A.C., **Troendle, J.F.**, & Zhang, J. (2006). Comparison of labor progression between induced and non-induced multiparous women. *Obstetrics and Gynecology*, *107*, 1029-1034.
- Kalantaridou, S.N., Calis, K.A., Vanderhoof, V.H., Bakalov, V.K., Corrigan, E.C., **Troendle, J.F.**, & Nelson, L.M. (2006). Testosterone deficiency in young women with 46,XX spontaneous premature ovarian failure. *Fertility and Sterility*, *86*, 1475-1482.
- Klebanoff, M.A., Andrews, W.W., **Yu, K.F.**, Brotman, R.M., Nansel, T.R., Zhang, J., Cliver, S.P., & Schwebke, J.R. (2006). A pilot study of vaginal flora changes with randomization to cessation of douching. *Sexually Transmitted Diseases*, *33*, 610-613.
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- Levine, R.J., Qian, C., Maynard, S.E., **Yu, K.F.**, Epstein, F.H., & Karumanchi, S.A. (2006). Serum sFlt1 concentration during preeclampsia and midtrimester blood pressure in healthy nulliparous women. *American Journal of Obstetrics and Gynecology*, *194*, 1034-1041.
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- Liu, A.**, Schisterman, E.F., & Wu, C.Q. (2006). Multistage evaluation of measurement error in a reliability study. *Biometrics*, *62*, 1190-1196.
- Mumford, S.L., Schisterman, E.F., Vexler, A., & **Liu, A.** (2006). Pooling biospecimens and limits of detection: Effects on receiver-operating characteristics curve analysis. *Biostatistics*, *7*, 585-598.
- Nansel, T.R., Riggs, M.A., **Yu, K.F.**, Andrews, W.W., Schwebke, J.R., & Klebanoff, M.A. (2006). The association of psychosocial stress and bacterial vaginosis in a longitudinal cohort. *American Journal of Obstetrics and Gynecology*, *194*, 381-386.
- Schisterman, E.F., Vexler, A., Whitcomb, B.W., & **Liu, A.** (2006). The limitations due to exposure detection limits for regression models. *American Journal of Epidemiology*, *163*, 374-383.
- Signore, C., Mills, J.L., Qian, C., **Yu, K.F.**, Lam, C., Epstein, F.H., Karumanchi, S.A., & Levine, R.J. (2006). Circulating angiogenic factors and placental abruption. *Obstetrics and Gynecology*, *108*, 338-344.
- Sundaram, R.** (2006). Estimation in two-sample randomly truncated scale model. *Journal of Statistical Planning and Inference*, *136*, 2983-3006.
- Sundaram, R.** (2006). Semiparametric inference in proportional odds model with time-dependent covariates. *Journal of Statistical Planning and Inference*, *136*, 320-334.
- Troendle, J.F.**, & **Yu, K.F.** (2006). Likelihood approaches to the nonparametric two-sample problem with right-censored data. *Statistics in Medicine*, *25*, 2284-2298.
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- Vexler, A., **Liu, A.**, & Schisterman, E.F. (2006). Efficient design and analysis of biospecimens with measurements subject to detection limit. *Biometrical Journal*, *7*, 780-791.

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2007

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- England, L.J., Grauman, A., Qian, C., Wilkins, D.G., Schisterman, E.F., **Yu, K.F.**, & Levine, R.J. (2007). Misclassification of maternal smoking status and its effects on an epidemiologic study of pregnancy outcomes. *Nicotine and Tobacco Research*, 9, 1005-1013.
- Ferrari, R.M., Cooney, M.A., Vexler, A., **Liu, A.**, & Buck Louis, G.M. (2007). Time-to-pregnancy and multiple births. *Human Reproduction*, 22, 407-413.
- Fleisch, A.F., Agarwal, N., Roberts, M.D., Han, J.C., Theim, K.R., Vexler, A., **Troendle, J.**, Yanovski, S.Z., & Yanovski, J.A. (2007). Influence of serum leptin on weight and body fat growth in children at high risk for adult obesity. *Journal of Clinical Endocrinology and Metabolism*, 92, 948-954.
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- Liu, A.**, Wu, C., **Yu, K.F.**, & Yuan, V. (2007). Completeness and unbiased estimation in multivariate group sequential case. *Journal of Multivariate Analysis*, 98, 505-516.
- Liu, A.**, Wu, C.Q., **Yu, K.F.**, & Yuan, V. (2007). Estimation following a multivariate group sequential test. *Journal of Multivariate Analysis*, 98, 505-516.
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- Neggers, Y.H., Nansel, T.R., Andrews, W.W., Schwebke, J.R., **Yu, K.F.**, Goldenberg, R.L., & Klebanoff, M.A. (2007). Dietary intake of selected nutrients affects bacterial vaginosis in women. *The Journal of Nutrition*, 137, 2128-2133.
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Klebanoff, M.A., Brotman, R.M., Zhang, J., Andrews, W., Yu, K.F., Schwebke, J.R., & **Nansel, T.R.** (in press). Race of male sex partner and occurrence of bacterial vaginosis. *Sexually Transmitted Diseases*.

Klebanoff, M.A., **Nansel, T.R.**, Brotman, R.M., Zhang, J., Yu, K.F., Schwebke, J.R., & Andrews, W.W. (in press). Personal hygienic behaviors and bacterial vaginosis. *Sexually Transmitted Diseases*

Mehta, S.N., **Haynie, D.L.**, Higgins, L.A., Bucey, N.N., **Rovner, A.J.**, Volkening, L.K., **Nansel, T.R.**, Laffel, L.M. (in press). Emphasis on carbohydrates may negatively influence dietary patterns in youth with Type 1 diabetes. *Diabetes Care*.

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Simons-Morton, B.G., Pickett, W., ter Bogt, T.F.M., Boyce, W., & Vollebergh, W.A.M. (in press). Cross-national comparison of adolescent drinking and *Cannabis* use in the United States, Canada, and the Netherlands. *International Journal of Drug Policy*.

Simons-Morton, B.G., Ouimet, M.C., **Wang, J.**, Klauer, S.G., Lee, S.E., & Dingus, T.A. (in press). Hard braking events among novice teenage drivers by passenger characteristics. *Driving Assessment*.

**APPENDIX D: PROFESSIONAL SERVICE ACTIVITIES BY DIVISION STAFF,
2005 THROUGH 2009**

OFFICE OF THE DIRECTOR

- Michele Kiely
 - o Chair, Site Visit Panel; National Center on Birth Defects and Developmental Disabilities (NCBDDD), Centers for Disease Control and Prevention (CDC); 2007
 - o Chair, Research Work Group, Research to Policy and Practice: Periodontal Health and Birth Outcomes; Maternal and Child Health Bureau (MCHB) of the Health Resources and Services Administration (HRSA); 2006
 - o Chair, Health Tomorrows Grant Review; MCHB, HRSA; 2003-2005
 - o Member; District of Columbia Department of Health Perinatal Advisory Committee; 2007
 - o American Co-Editor; *Paediatric and Perinatal Epidemiology*; 2001-2007
 - o Chair, Maternal and Child Health Systematic Reviews Panel; Tulane University; 2007
- Maurice Davis
 - o Panel Member, Minority Health Symposium; Morgan State University; 2007
 - o Panel Moderator; Minority Health Foundation Conference; 2006
 - o Panel Member; Healthy Teen Network Annual Conference; 2005

BIostatistics & Bioinformatics Branch (BBB)

Tenure-Track Investigators

- Zhen Chen
 - o Judge; Fellows Award for Research Excellence, Epidemiology Section; 2009
 - o Scientific Committee; the 7th International Conference on Health Policy Statistics; 2008
- Rajeshwari Sundaram
 - o Member, Search Committee; Staff Scientist Epidemiology Branch; 2008
 - o Member, Intramural Research Training Award Evaluation Committee; Division of Epidemiology, Statistics, and Prevention Research (DESPR); 2008
 - o Member, Search Committee; BBB Chief; 2009
 - o Newsletter Editor; International Indian Statistical Association; 2006
 - o Director, Young Professionals; International Indian Statistical Association; 2007
 - o Associate Editor; *Biometrics*; 2008-Present

Tenured Investigators

- Paul Albert
 - Member, Protocol Review and Monitoring Committee; Center for Clinical Research, National Cancer Institute (NCI); 2005-2008
 - Member, Intramural Pulmonary Data Safety and Monitoring Board (DSMB); National Heart, Lung, and Blood Institute (NHLBI); 2005-2006
 - Member, DSMB, trial on valacyclovir for treating herpes simplex encephalitis; National Institute of Allergy and Infectious Disease (NIAID); 2005-2009
 - Reviewer; National Sciences and Engineering Research Council of Canada; 2005 & 2008
 - Associate Editor; *Statistics in Medicine*; 2005-Present
 - Member; Eastern North American Region/International Biometric Society Program Committee; 2010
 - *Ad hoc* Tenure Review Panel; Department of Statistics, University of Medicine and Dentistry of New Jersey; 2006
 - *Ad hoc* Promotions Review Panel; Fred Hutchinson Cancer Center; 2007
 - *Ad hoc* Promotion Review Panel; Department of Quantitative Health Sciences, Cleveland Clinic Foundation; 2008
 - *Ad hoc* Tenure Review Panel; Department of Health Administration and Policy; 2009
- Aiyi Liu
 - Judge; Fellows Award for Research Excellence, Gene Expression Section; 2005
 - Member, Search Committee; National Institute on Aging (NIA); 2005 & 2006
 - Member, Search Committee; DESPR; 2006
 - Member, DSMB, *S. japonicum* and Pregnancy Outcomes: A Randomized, Double Blind Placebo-Controlled Trial; NIAID; 2006-Present
 - *Ad hoc* Reviewer, Board of Scientific Counselors (BSC); NIA; May 2008
 - Member, Search Committee Member; Tenure-track Investigator, BBB; 2009
 - Member, Planning Committee; International Chinese Statistical Association (ICSA) Applied Statistics Symposium; 2005
 - Member, Board of Directors; ICSA; 2007-2009
 - Guest Editor, *Mathematical and Statistical Methods for Diagnoses and Therapies*, Special Theme Issue; Philosophical Transaction of the Royal Society A; 2007
 - Associate Editor; *Journal of Statistical Planning and Inference*; 2009-Present
- James Troendle
 - Member, Search Committee; NICHD; 2005
 - Special Consultant, Intramural DSMB; National Human Genome Research Institute (NHGRI); 2005-present
 - Grant Reviewer; National Science Foundation (NSF); 2005
- Kai Yu
 - Member, Institutional Review Board; NICHD
 - Member, Scientific Review Group; Pediatric, Adolescent, and Maternal AIDS Branch, NICHD
 - *Ad hoc* Member, Tenure and Promotion Committee; National Eye Institute
 - Grant Proposal Reviewer; NSF; 2005

- o Member, Scientific Program Committee; First and Second International Workshop on Sequential Methodologies; 2007-2009
- o Organizer, Invited Papers Session; First International Workshop on Sequential Methodologies; 2007
- o Member, Advisory Panel; International Workshop on Sequential Methodologies; 2007-Present

EPIDEMIOLOGY BRANCH

Tenure-Track Investigators

- Cuijin Zhang
 - o NICHD Representative; NIH Roadmap Genotyping/Gene Expression Working Group
 - o Member, Obesity Research Strategic Core; Office of the Director, NICHD; 2008-Present
 - o Expert Panelist, Gestational Diabetes Beyond Pregnancy Conference; CDC
 - o Editorial Board Member, Academic Editor; *Public Library of Science (PLoS) ONE*
 - o Member, Grant Review Panel; Michigan Diabetes Research and Training Center; 2008 & 2009

Tenured Investigators

- Mark Klebanoff
 - o Member, Search Committee; Nutritional Epidemiology Branch, NCI; 2005
 - o Division of Intramural Research (DIR) Representative, Tenure-track Investigator's Review; NCI
 - o Member, External Epidemiology Advisory Panel; NIAID; 2005
 - o Member, DSMB; Division of Microbiology and Infectious Disease, NIAID; 2006-Present
 - o Member, Neonatal Research Network Advisory Board; NICHD; 2000-Present
 - o Member, Epidemiology-Biometry Promotion and Tenure Review Board; NIH; 2000-Present
 - o Study Section Member, Genetic Association Information Network; NIH Foundation; 2006
 - o Site Visit Panel; NCBDDD, CDC; 2007
 - o Director, Search Committee; Division of Reproductive Health, CDC; 2008
 - o Reviewer, Report on Vaginal Birth After Cesarean Section; Agency for Health Care Research and Quality (ARHQ); 2009
 - o Editorial Board; *American Journal of Epidemiology*; 2000-Present
 - o Abstract Review; Society for Paediatric and Perinatal Epidemiology Research (SPER); 2004-2009
 - o Abstract Review; Society for Maternal-Fetal Medicine (SMFM); 2005-2009
 - o Abstract Review; Society for Epidemiological Research (SER); 2005-2009
 - o *Ad hoc* Reviewer, Program Project Grant in the Epidemiology of Preterm Birth; Institute of Human Development, Child, and Youth Health, Canadian Institutes of Health Research; 2005

- o *Ad hoc* Reviewer, Clinical Trial of Vaginal Progesterone to Prevent Recurrent Preterm Birth; British Medical Research Council; 2005
- o Member, Scientific Advisory Board on Preterm Birth; March of Dimes; 2002-Present
- o Spotlight Session Coordinator, Reproductive Epidemiology; SER; 2005
- o Judge, Fellows' Plenary Session; SMFM; 2007
- o Spotlight Session Coordinator, Environmental Influences on Reproductive Outcomes; SER; 2009
- o Abstract Review; Pediatric Academic Societies; 2009-2010
- o Grant Reviewer; Thrasher Foundation; 2006
- o Awards Committee; Coalition for Excellence in Maternal and Child Health Epidemiology; 2006-Present
- o Scientific Advisory Board; Burroughs Wellcome Fund Research Consortium on Preterm Birth; 2007-Present
- o Howard Hughes Medical Institute-NIH Research Scholars Program Advisory Committee; 2006-Present
- o Scientific Advisory Committee; Seattle Children's Hospital Office for the Prevention of Stillbirth and Preterm Birth; 2008-2009
- Richard Levine
 - o Member, Search Committees; NICHD
 - o Trans-NIH Angiogenesis Research Program; NIH
 - o Angiogenesis Workshop Organizing Committee; NIH
 - o Co-Chair, Trans-NIH Translational Research Interest Group; NIH
 - o Workshop Organizer; International Society for the Study of Hypertension in Pregnancy
 - o Member, Peer-Review Panel; The National Academies
 - o Member, Peer-Review Panel; Israeli-Palestinian Science Organization
 - o International Referee; Research Grants Council of Hong Kong, Medical Research Council of South Africa, British Heart Foundation, New Zealand Centres of Research Excellence Fund, and Medical Research Council of the United Kingdom
- Germaine Buck Louis
 - o Member, Search Committees; NICHD & NCI
 - o Tenure Review Committees; NIH
 - o Women Scientist Advisors; 2000-Present
 - o 2nd Task Force on Status Intramural Women Scientists; 2003-2006
 - o Working Group on Women in Biomedical Careers; NIH; 2007-Present
 - o Subcommittee for Recruitment, Retention, and Advancement of Women at NIH; Office of Intramural Research, NIH; 2007-2009
 - o DIR-designated NIH Scientific Representative, Board of Scientific Counselors; Division of Cancer Epidemiology & Genetics (DCEG), NCI; 2005, 2007, 2008
 - o Grant Reviewer, Special Emphasis Panel; MRC, NICHD, & the National Toxicology Program (NTP), National Institute of Environmental Health Sciences (NIEHS); 2007-2008
 - o Science Advisory Panel; Assisted Human Reproduction Canada; 2008-2010
 - o Scientific Advisory Board; U.S. Environmental Protection Agency (EPA); 2003-2009
 - o BSC; NTP, NIEHS; 2005-2007

- o Grant Reviewer; U.S. Agency for International Development; 2007
- o Consultant, Human Studies Review Board; EPA; 2007
- o Associate Editor; *American Journal of Epidemiology*; 2001-Present
- o Councilor; International Society for Environmental Epidemiology (ISEE); 2004-2007
- o Panel Member; The National Academies; 2006, 2009-Present
- o Awards Committee and Student Prize Paper Committee; Epidemiology Congress; 2006
- o Chair, ISEE Nominations Committee; ISEE; 2006
- o Awards Committee; ISEE; 2007
- o Grant Peer Reviewer; Thrasher Foundation; 2004
- o Grant Peer Reviewer; Medical Research Council; 2007
- o Abstract Reviewer; ISEE, SPER, SER, & European Society for Human Reproduction and Embryology; 2004-Present (society varies by year)
- o Awards Committee; SPER; 2009
- James Mills
 - o *Ad hoc* Tenure Committee; 2007
 - o Peer Reviewer; NHGRI; 2008
 - o Executive Secretary, Data Safety and Monitoring Committee
 - o Cultivating Healthy Eating in Families (CHEF) Study; 2009
 - o Judge; FARE (Fellow's research competition); 2009
 - o Expert Panel; Food and Drug Administration (FDA); 2006
 - o Advisory Group; CDC; 2007
 - o Expert Reviewer; AHRQ/U.S. Preventive Services Task Force Program; 2007
 - o Reviewer, 2nd Technical Workshop Report on Folic Acid Fortification; CDC; 2008
 - o Public Affairs Committee; Teratology Society; Ongoing
 - o Membership Committee; American Epidemiological Society; 2004-2008
 - o Organizer and Chair, Public Affairs Committee Symposium; Teratology Society; 2007-2008
- Enrique Schisterman
 - o Search Committees; NICHD & NIH
 - o Search Committee; NCI
 - o DIR-designated NIH Scientist Representative, Tenure Track Reviews; DCEG, NCI
 - o Associate Editor; *American Journal of Epidemiology*; 2004-2011
 - o Associate Editor; *Epidemiology*; 2005-2011
 - o Guest Editor; *Epidemiology*; 2008-2010
 - o Student Workshop Organizer; SPER; 2005-2010
 - o Scientific Advisor Board Member, Middle East Cerebral Palsy Study; United Cerebral Palsy Association; 2008-2009
 - o Student Prize Committee; SER; 2007
- Jun (Jim) Zhang
 - o Search Committees; NICHD
 - o DSMB; Reproductive Medicine Network, NICHD
 - o Advisory Board; Neonatal Research Network, NICHD

- o Member, Maternal, Infant, and Child Health Focus Group; CDC-U.S. Department of Health and Human Services Healthy People 2010
- o Grant Reviewer; Canadian Institute of Health Research & NIAID
- o Member, Reproductive Health Measures Working Group; PhenX Project, NHGRI
- o Finance Committee; American College of Epidemiology
- o Associate Editor; *American Journal of Epidemiology*
- o Technical Expert Panel, Evidence-Based Practice Center Review on Elective Induction of Labor and Vaginal Birth after Previous Cesarean Delivery
- o Board Member, External Advisory Committee; Integrated Research Network in Perinatology of Quebec and Eastern Ontario, Canada

Scientific Staff

- Mary Hediger
 - o Steering Committee, Bone Mineral Density in Childhood Study; Endocrinology, Nutrition, and Growth Branch, Center for Research for Mothers and Children, NICHD
 - o Panelist, Workshop on Epidemiology of Communication Disorders; National Institute on Deafness and Other Communication Disorders; 2005
 - o Reviewer; Global Network for Women's and Children's Health Research, NICHD; 2007
 - o *Ad hoc* Reviewer; Neurological, Aging, and Musculoskeletal Epidemiology (NAME) Study Section, Center for Scientific Review (CSR); 2008
 - o Domain Expert, Anthropometrics Working Group of PhenX: Consensus measures for Phenotypes and eXposures Project; PhenX Project, NHGRI; 2008-2009
 - o Core Member and Workshop Planning Committee, Anthropometry and Body Composition Working Group; National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK); 2008-Present
 - o Member, Obesity Research Strategic Core; Office of the Director, NICHD; 2008-Present
 - o Reviewer (Regular Member); NAME Study Section, CSR; 2009
 - o Panelist, National Health and Nutrition Examination Survey Pubertal Maturation Workshop for Development of a Self-Assessment Component; National Center for Health Statistics (NCHS), CDC; 2005
 - o Panelist, Expert Panel Review of Growth Charts, Evaluation of the World Health Organization Child Growth Standards and CDC Growth Charts; NCHS, CDC; 2006
 - o Expert Peer Reviewer, Evidence Report: Systematic Review on Maternal & Child Health Outcomes Associated with Maternal Weight Gain; AHRQ and American Dietetic Association (ADA); 2007
 - o President; SPER; 2005-2006
 - o Panelist, Workshop on the Impact of Pregnancy Weight on Maternal and Child Health; National Research Council, The National Academies; 2006
 - o Guest Editor, Addressing Gestational Age Measurement Using Birth Certificate Data; *Paediatric and Perinatal Epidemiology*; 2007
 - o External Reviewer; Canadian Institute of Health Research/Canadian Foundation for Innovation; 2007
 - o Editorial Board; *Annals of Human Biology*; 2008-2009

- o External Reviewer; Research Fund Secretariat, Hong Kong; 2009
- Una Grewal
 - o Search Committee, NICHD

PREVENTION RESEARCH BRANCH

Tenure-Track Investigators

- Tonia Nansel
 - o Tenure-track Investigators Committee; NIH
 - o Expert Panel Member, Toward a Working Definition of the Metabolic Syndrome in Children and Adolescents; NICHD, NIDDK, NHLBI, Office of Rare Disease Research
 - o Consortium of the Behavioral and Social Sciences; NICHD
 - o Member, Obesity Research Strategic Core; Office of the Director, NICHD
 - o Search Committee, BBB Investigator; DESPR
 - o Search Committee, Epidemiology Branch Chief; DESPR
 - o Invited Moderator, Insulin Pump Safety Meeting; , FDA
 - o Health and Safety Organizations Implementation Working Group Subcommittee, HRSA's National Bullying Prevention Campaign
 - o *Ad hoc* Grant Reviewer; ADA Healthy Food Choices
 - o *Ad hoc* Grant Reviewer; Sam Houston State University Enhancement Grant for Research
 - o Grant Reviewer; Behavioral Research in Diabetes Group Exchange Travel Grant
 - o *Ad hoc* Grant Reviewer; Health Research Board, Ireland
 - o Co-president; Behavioral Research in Diabetes Group Exchange
 - o Treasurer; Behavioral Research in Diabetes Group Exchange
 - o Invited Session Chair, American Diabetes Association

Tenured Investigators

- Bruce Simons-Morton
 - o DIR Representative, Tenure-track Investigator Search Committee; NHGRI
 - o Chair, Search Committee, BBB Chief; DESPR
 - o Site Visitor, Behavioral and Social Science Research Group (BSSRG); NHGRI
 - o Chair, Search Committee, BSSRG; NHGRI
 - o NIH Representative, DSMB; Effects of Aspirin in Gestational and Reproduction Trial
 - o Member, Expert Review Panel for Site Visit; University of Alabama, Birmingham Injury Center, CDC; 2006.
 - o Member, Expert Panel, Teen Health Media Project; CDC
 - o Reducing High-Risk Behaviors Among Teenage Drivers; Center for Injury Prevention and Control, CDC
 - o Member, Annual Meeting Planning Committee, Young Driver Subcommittee; Transportation Research Board, National Academy of Sciences; 2010

The information in this document is no longer current. It is intended for reference only.

- o Member, Planning Committee, National Invitational Conference on Graduated Driver Licensing; National Safety Council; 2007
- o Member, Expert Panel, Improving Safety Belt Use Among Adolescents; National Safety Council; 2006
- o Appointed Member, Committee on Operator Education and Regulation; Transportation Research Board; 2006-Present
- o Member, Expert Panel, Strategic Planning Conference; American Automobile Association Foundation; 2006-Present
- o Member, Expert Panel on Young Drivers; State Farm Insurance Company;
- o Editorial Board; *American Journal of Health Behavior & Health Education & Behavior*

Scientific Staff

- Ronald Iannotti
 - o Intramural Clinical Research Program Scientific Review; NICHD
 - o Consortium of the Behavioral and Social Sciences; NICHD
 - o Member, Obesity Research Strategic Core; Office of the Director, NICHD
 - o Member, Expert Panel, NICHD Feeding Families: Bridging Social Sciences and Social Epidemiology Approaches to Obesity Research; NICHD
 - o Interagency Coordinating Committee; National Children's Study; NICHD
 - o Review Board; *American Journal of Health Promotion*
 - o Editorial Board; *The Prevention Researcher*
 - o Treasurer; International Society of Behavioral Nutrition and Physical Activity
 - o Member, Expert Panel; American Association of Diabetes Educators
- Denise Haynie
 - o Web Site Committee; Prevention Research Branch, DESPR
 - o Contract Reviewer; Office of Science Policy, Analysis, and Communications, Office of the Director, NICHD; June 2007
 - o Prevention Fingerprint Committee; Research, Condition, and Disease Categorization, NIH; 2007
 - o Reviewer; Graduate Student Research Festival; 2008, 2009
 - o Member, Search Committee, Staff Scientist; Epidemiology Branch, DESPR
 - o Review Panel, American Recovery and Reinvestment Act Challenge Grants; NICHD; 2009
 - o National Committee on School Health; 2005-Present
 - o Johns Hopkins Center for the Prevention of Violence Working Group; 2005-Present
 - o *Ad hoc* Grant Reviewer; NSF; 2008
 - o *Ad hoc* Grant Reviewer; William T. Grant Foundation; 2009

APPENDIX E: DIVISION STAFF AWARDS AND HONORS, 2005 THROUGH 2009

OFFICE OF THE DIRECTOR

- 2006, Michele Kiely, Surgeon General's Certificate of Appreciation for Excellent Service in Support of the Surgeon General Initiative, Year of the Healthy Child
- 2006, Maurice Davis, NICHD Merit Award for Exemplary Leadership, Notable Competence, and Resourcefulness in Improving the Operational Objectives of the NIH-D.C. Initiative

BIostatistics & Bioinformatics Branch (BBB)

- 2005, Albert, Elected Fellow of American Statistical Association
- 2005, Liu, Elected to International Statistical Institute
- 2005, Troendle, Elected to International Statistical Institute
- 2007, Hyun (Fellow, Mentor: Sundaram), Best Student Presentation Award, Probability and Statistics Day, University of Maryland, Baltimore County
- 2007, Liu Wu (Fellow), NICHD Merit Award for Creative Epidemiologic Design and Methodologic Rigor in the Successful Completion of the BioCycle Study
- 2007, Yu, Elected Fellow of American Statistical Association
- 2008, Lum (Fellow, Mentor: Sundaram), Wray Jackson Smith Award (sponsored by American Statistical Association)
- 2009, Chen Liu (Fellow, Mentor: Sundaram), NICHD Merit Award for Ingenuity in Designing and Dedication in Completing the LIFE Study, Whose Aim Is To Identify Environmental Reproductive Toxicants

EPIDEMIOLOGY BRANCH

- 2005, Levine, NIH Director's Award for Scientific Advances in Understanding the Pathogenesis of Preeclampsia
- 2005, Klebanoff, National Maternal and Child Health Epidemiology Advancing Science Award, Coalition for Excellence in Maternal and Child Health Epidemiology
- 2005, Hediger, Buck Louis, Klebanoff, Schisterman, and Zhang, NICHD Merit Award for Innovative Planning and Dedication to the Successful Development of the First NICHD/Institute of Human Development, Child, and Youth Health-Sponsored Summer Institute for Reproductive and Perinatal Epidemiology
- 2006, Bloom (Fellow, Mentors: Schisterman & Hediger), Student Prize Paper Award, Society for Pediatric and Perinatal Epidemiologic Research; also Outstanding Paper Contribution, *Fertility and Sterility*

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- 2006, Levine, Award of Research Excellence, Society for Maternal-Fetal Medicine
- 2006, Hediger, Charlotte Promersberger-Johnson Lecturer, 2006 Children's Hospital of Wisconsin, Medical College of Wisconsin
- 2006, Whitcomb (Fellow), Poster Presentation Award, Society for Epidemiologic Research
- 2007, Hediger, Schisterman, Perkins (Fellow), and Whitcomb (Fellow), NICHD Merit Award for creative epidemiologic design and methodologic rigor in the successful completion of the BioCycle study
- 2007, Buck Louis, A. Marsh Poulson, Jr. Lectureship, University of Utah
- 2007, Brotman (Fellow, Mentor: Klebanoff), Fellows Award for Research Excellence, NIH Research Festival
- 2008, J. Zhang, Elected to the American Epidemiological Society
- 2008, Perkins (Fellow), Poster Presentation Award, Society for Epidemiologic Research
- 2009, Buck Louis, Chen (BBB), Liu (BBB), Schisterman, Sundaram (BBB), NICHD Merit Award for Ingenuity in Designing and Dedication in Completing the LIFE Study, Whose Aim Is To Identify Environmental Reproductive Toxicants
- 2009, Gollenberg (Fellow) and Pollack (Fellow), Abstract Award, Society of Toxicology

PREVENTION RESEARCH BRANCH

- 2005, Simons-Morton
 - Rockefeller Foundation Scholar-in-Resident at Bellagio, Italy
 - Public Health Scholar, University of North Carolina, Charlotte
 - Fellow, American Academy of Health Behavior
- 2006, Simons-Morton
 - President, American Academy of Health Behavior
 - Distinguished Visiting Professor, University of North Carolina, Chapel Hill, Transportation Research Institute
- 2006, Rovner (Fellow, Mentor: Nansel), Young Investigator Award, American Society of Bone and Mineral Research
- 2006, Ouimet (Fellow), Certificate of Academic Excellence for an Exceptional Quality Doctoral Thesis, Canadian Psychological Association
- 2007, Simons-Morton
 - Research Laureate, American Academy of Health Behavior
 - Distinguished Visiting Professor, University of Iowa School of Public Health
 - Distinguished Visiting Professor, University of Minnesota Transportation Research Institute
- 2007, Iannotti, NIH Award of Merit for Exemplary Competence, Initiative, and Resourcefulness in Contributing to the Management of the Division during Periods of Significant Administrative Transition

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- 2009, Rovner (Fellow, Mentor: Nansel), Poster of Distinction, American Academy of Health Behavior
- 2009, Iannotti, NIH Award of Merit for Exemplary Initiative, Resourcefulness, and Competence in Developing and Funding Collaborative International and National Projects Engaging Multiple Institutes and Agencies

APPENDIX F: DIVISION STAFF SYMPOSIA, SCIENTIFIC SESSIONS, INVITED SPEECHES, AND OTHER ACTIVITIES, 2005 THROUGH 2009

BIostatistics & Bioinformatics Branch

- Paul Albert
 - Organized Invited Session, *Recent Advances in Two-Part Models*, Western North American Regional Conference, Biometry, spring meetings, 2005
 - Organized Invited Session, *Recent Advances in Analyzing Biomarker Data with Detection Limits*, Eastern North American Regional (ENAR) Conference, Biometry, spring meeting, 2008
 - Two Invited Seminars
- Zhen Chen
 - Session Organizer and Chair, *Recent Advances in Modeling Longitudinal Data*, 15th International Conference of Interdisciplinary Mathematical & Statistical Techniques, 2007
 - Two Invited Talks
- Aiyi Liu
 - Session Organizer and Chair, *Pooling Biospecimens: Methodologies, Applications and Limitations*, International Chinese Statistical Association (ICSA) Applied Symposium, 2005
 - Session Organizer and Chair, *Sequential Methods for Evaluation of Diagnostic Biomarkers*, ICSA Applied Symposium, 2006
 - Session Organizer, *Dealing with Measurements Subject to Limits of Detection in Epidemiology Studies*, ICSA Applied Symposium, June 2007
 - Short Course, *Sequential Statistical Methods in the Design and Analysis of Clinical Trials*, 15th International Conference on Interdisciplinary Mathematical and Statistical Techniques, 2007
- Rajeshwari Sundaram
 - Invited Session Organizer and Chair, *Multistage Modeling of Complex Biomedical Data*, ENAR, 2008
 - Session Moderator, *Study Designs and Methodological Challenges*, Preconception Care Research Workshop, NICHD, 2008
 - Session Organizer, *Statistical Methods in Reproductive Epidemiology*, Joint Statistical Meeting (JSM), 2009
 - Session Organizer, Panel Discussion: *Research in NIH*, JSM, 2009
- Kai Yu
 - Invited Session Organizer, *Sequential Clinical Trials*, First International Workshop on Sequential Methodologies

BIostatistics & Bioinformatics Branch, Scientific Presentations and Invited Talks

Name	Platform Presentations	Invited Seminars	Invited Talks
Albert		2	
Chen			2
Kim	13	3	
Liu	5	11	11
Sundaram	6	7	4
Troendle		1	2
Yu	6		2
Zhang			1

Epidemiology Branch

- Mary Hediger
 - o *Insights from the Epidemiology of Asthma: Population-Based Approaches to Prevention of the Disease*, joint Society for Pediatric & Perinatal Epidemiologic Research (SPER)—American Academy of Pediatrics Section on Epidemiology Symposium, 2nd North American Congress of Epidemiology, June 2006 (organized with Cabana, O’Shea, Siega-Riz, & England and with support from Novartis Pharmaceuticals)
- Mark Klebanoff
 - o Plenary Session Co-Organizer, *Emerging Environmental Issues in Perinatal and Child Health: Questions, Quandaries and Quagmires*, 15th Annual Maternal and Child Health Epidemiology Conference, December 2009
- Germaine Buck Louis
 - o Organizing & Planning Committee, *Prenatal Care Research: Improving Birth Outcomes and Reproductive Health Workshop*, NICHD, 2008
 - o Organizing & Planning Committee, *Team Science: Passion for Participatory Research*, NICHD, 2008
 - o Scientific Programme Committee Member, International Society for Environmental Epidemiology (ISEE), 2005
 - o Advisory & Planning Committee, University of California, San Francisco, and the Collaborative on Health and the Environment Summit, *Environmental Challenges to Reproductive Health and Fertility*, 2006-2007
 - o Organizer, Round Table, *Is Human Fecundity Declining and What are the Implications for Early Onset Disease?*, Society for Epidemiologic Research (SER), 2007

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- Enrique Schisterman
 - o Organizer and Chair, *Evaluation of Biomarkers in Epidemiological Research*, SER, 2005
 - o Advanced Students' Methods Workshop, jointly sponsored by SPER and the American Statistical Association Epidemiology Section, 2006, 2007, 2008, 2009
 - o Advanced Epidemiological Methods Training, University of Santiago de Chile, 2008, 2009
 - o Organizer and Chair, *Evaluation of Biomarkers Subject to Limit of Detection*, SER, 2008
- Courtney Lynch
 - o Session Organizer, *Methodologic Challenges in Reproductive and Perinatal Epidemiology*, 2nd North American Congress of Epidemiology, June 2006
- Ondine von Ehrenstein
 - o Organizer and Co-Chair, *Health Impact of Violence on Individuals and Communities: Methods of Early Assessment and Intervention*, ISEE, 2007
- Richard Levine
 - o Organizer and Chair, *Signaling*, Trans-Institute Angiogenesis Research Program Workshop on Inflammation and the Perivascular Environment, November 2007
 - o Organizer, Debate on *Anti-Angiogenic State in Preeclampsia*, International Society for the Study of Hypertension in Pregnancy World Congress, 2008

EPIDEMIOLOGY BRANCH, SCIENTIFIC PRESENTATIONS AND INVITED TALKS

Name	Platform Presentations	Invited Seminars	Invited Talks	Keynote Addresses
Buck Louis	4	9	20	2
Grewal	1			
Hediger	3	1	7	
Klebanoff	1		15	
Levine	11	4	2	5
Mills		5	4	
Perkins	2	1		
Schisterman	8	9	4	
Zhang (J)	2	4	1	
Zhang (C)	2	4	2	

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PREVENTION RESEARCH BRANCH

- Bruce Simons-Morton
 - o Symposium Organizer, *Parental Involvement with Novice Young Driving*, Transportation Research Board, National Academy of Sciences, 2009
- Ronald Iannotti
 - o Symposia Organizer, *Health Behaviour in School-Aged Children: International Perspectives on Research and Health Policy in Diet and Physical Activity*, International Society of Behavioral Nutrition and Physical Activity, 2008

PREVENTION RESEARCH BRANCH, SCIENTIFIC PRESENTATIONS AND INVITED TALKS

Name	Platform Presentations*	Invited Seminars	Invited Talks	Keynote Addresses
Simons-Morton	5	4	8	2
Haynie		2	3	
Iannotti	9		2	1
Nansel	6	4	2	
Wang	1			

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