

EGRP Bulletin

Epidemiology and Genetics Research Program

Web Site: <http://epi.grants.cancer.gov>

The Epidemiology and Genetics Research Program (EGRP), in the National Cancer Institute's (NCI) Division of Cancer Control and Population Sciences (DCCPS), provides research opportunities to increase understanding of cancer etiology and prevention in human populations. EGRP supports epidemiologic research in four areas:

Modifiable Risk Factors—focusing on factors that may be modified to reduce cancer risk, such as diet and nutrition; alcohol; physical activity and energy balance; tobacco; infectious diseases; physical and chemical agents; and medical exposures, including medications and treatments;

Host Susceptibility Factors—focusing on factors that influence personal susceptibility to cancer, such as genetic, epigenetic, immunological, hormonal, and biological pathways; and social, cultural, and racial/ethnic factors;

Methods and Technologies—focusing on methods for epidemiologic data collection, study design and analysis, and development and adaptation of laboratory and technical approaches for large epidemiologic studies; and

Clinical and Translational Epidemiology—focusing on factors that influence development of cancer among persons with underlying diseases and conditions; progression, recurrence, and mortality from cancer; and development of new primary cancers.

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Funding Opportunities of Interest

Replication and Fine-Mapping Studies for the Genes, Environment, and Health Initiative

The National Institutes of Health (NIH)-wide Genes, Environment, and Health Initiative (GEI), <http://www.gei.nih.gov>, released a Funding Opportunity Announcement (FOA) to provide support for replication and fine-mapping studies of genetic regions that putatively are associated with common complex traits, such as those identified by genome-wide association studies (GWAS). The FOA solicits applications for projects aimed at enhancing the identification of causal variants that influence complex diseases. Because it is an NIH-wide initiative, any phenotype may be appropriate for these projects (i.e., studies need not be oriented toward cancer or cancer-related phenotypes). The emphasis is on followup studies that are needed to replicate and validate initial GWAS findings to: (a) eliminate false positive associations, (b) narrow the association intervals of interest, and (c) extend the findings to diverse populations (such as diversity in race, ethnicity, or environmental exposures) and related phenotypes. Only a replication study alone, or a replication study plus a fine-mapping effort, may be proposed.

This FOA will not support recruiting human subjects, collecting human specimens, collecting medical or phenotypic data, studies using animal models, or discovery genome-wide association efforts. Investigators are expected to have access to phenotypic and exposure data and DNA sources from an

existing study population(s) of sufficient size at the time of application to adequately address the specific aims. Well-designed replication studies should follow the NCI-National Human Genome Research Institute (NHGRI) Working Group on Replication in Association Studies' guidelines (<http://www.nature.com/nature/journal/v447/n7145/full/447655a.html>) for what constitutes replication of a genotype-phenotype association and how it can best be achieved.

Using the NIH Research Project Grant (R01) funding mechanism, this FOA focuses on discrete, specified, circumscribed projects based on strong preliminary data. Unlike typical multiyear R01 projects, however, this FOA solicits applications solely for projects that can be completed in one funding period, not to exceed 12 months.

This FOA is administered by NCI, but was developed as part of the NIH-wide GEI. Applications are due by December 1, 2008. The contact for inquiries is EGRP's Elizabeth Gillanders, Ph.D., Program Director, Host Susceptibility Factors Branch, e-mail: lgilland@mail.nih.gov.

Access the *NIH Guide for Grants and Contracts* for details: RFA-CA-09-003 (R01): <http://grants.nih.gov/grants/guide/rfa-files/RFA-CA-09-003.html>.

Grantsmanship

NIH Data Sharing Policy In Effect for Genome-Wide Association Studies

The new policy for the sharing of data obtained through NIH-supported or -conducted genome-wide association studies (GWAS) went into effect in January 2008. The policy applies to: competing grant applications that include GWAS and are submitted to NIH for the January 25, 2008, and subsequent due dates; proposals for contracts that include GWAS and are submitted to NIH on or after January 25, 2008; and NIH intramural research projects that include GWAS and are approved on or after January 25, 2008.

The final policy was announced in the *NIH Guide*, NOT-OD-7-088, after a period of public consultation with representatives from the scientific and lay communities. A followup Notice, NOT-OD-08-013, provides guidance on implementation and instructions for applicants. Access these Notices at <http://grants.nih.gov/grants/guide>.

The policy's goal is to facilitate broad and consistent access to NIH-supported GWAS data to speed the translation of basic genetic research into therapies, products, and procedures that benefit the public health. NIH believes that the full value of GWAS to the public can be realized only if the resulting genotype and phenotype datasets are made available as rapidly as possible to a wide range of scientific investigators. Rapid and broad data access are particularly important for GWAS—these studies generally require significant resources, present challenges in analyzing the large datasets, and provide extraordinary opportunities for making comparisons across multiple studies.

Refer to the NIH GWAS Web site at <http://grants.nih.gov/grants/gwas> for guidance on implementing the policy, including developing data-sharing plans for applications and proposals

that include GWAS, peer review of GWAS grant applications, submitting data to the NIH GWAS data repository, requesting access to data in the NIH GWAS data repository, oversight of the NIH GWAS initiative, protections for research

participants, points to consider for Institutional Review Boards and institutions in their review of data submission plans and institutional certifications, and frequently asked questions and answers.

New NIH Policy To Fund Meritorious Science Earlier

On October 8, 2008, NIH announced that beginning with original new applications (i.e., never submitted) and competing renewal applications submitted for the January 25, 2009, due dates and beyond, NIH will accept only a single amendment (A1) to the original application. Failure to receive funding after two submissions (i.e., the original and the single amendment) will mean that the applicant should substantially redesign the project rather than simply change the application in response to previous reviews. It is expected that this policy will lead to funding high-quality applications earlier, with fewer resubmissions.

Original new and competing renewal applications that were submitted prior to January 25, 2009, will be permitted two amendments (A1 and A2). For these “grandfathered” applications, NIH expects that any A2 will be submitted no later than January 7, 2011; NIH will not accept A2 applications after that date.

This policy applies to **all** applications, including those submitted under the NIH Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs, Career Development Awards, Individual Fellowships,

Institutional Training Grants, Resource Grants, Program Projects, and Centers. Currently, no amendments are permitted for applications received in response to a Request for Applications (RFA) unless it is specified in the Funding Opportunity Announcement, in which case only one amendment will be permitted.

Applicants are strongly encouraged to discuss their questions with their NIH Institute or Center contact. For additional information or questions, send an e-mail to: EnhancingPeer_Review@mail.nih.gov or contact:

Division of Receipt and Referral
Center for Scientific Review
6701 Rockledge Drive, MSC 7720
Bethesda, MD 20892-7720
Voice: 301-435-0715
Fax: 301-480-1987

The new policy was announced in the *NIH Guide for Grants and Contracts*, NOT-OD-09-003, which can be accessed at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-003.html>.

NIH Revised Policy Issued on Enhancing Public Access to Archived Publications

The NIH Public Access Policy requires that all final peer-reviewed manuscripts arising from NIH funds be submitted to PubMed Central (PMC, <http://pubmedcentral.nih.gov>) on acceptance for publication. As of May 25, 2008, all NIH applications, proposals, and progress reports must include the PMC reference number or NIH Manuscript Submission reference number when citing a paper that falls under the policy and is authored or co-authored by the investigator, or arose from the investigator’s NIH award.

Key Public Access Policy Web pages:

- Home page: <http://publicaccess.nih.gov/index.htm>
- Frequently Asked Questions: <http://publicaccess.nih.gov/FAQ.htm#content>
- Communications and Training: <http://publicaccess.nih.gov/communications.htm>
- NIH Guide Notice, NOT-OD-08-033: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-033.html>

Grant Applications Must Tie to Funding Opportunity Announcements

Together with implementation of electronic submission of grant applications, remember that all applications must be submitted in response to specific Funding Opportunity Announcements (FOAs). NIH has omnibus parent announcements for use in submitting what formerly were

termed “unsolicited” applications. For help in identifying appropriate FOAs for unsolicited or investigator-initiated applications, see http://grants.nih.gov/grants/guide/parent_announcements.htm, or consult your EGRP Program Director.

NIH Summarizes Policy on Late Grant Applications

NIH describes its policy on late grant applications in a Notice in the *NIH Guide*, consolidating information from previous Notices. Investigators are reminded that no NIH staff member, whether in the Center for Scientific Review (CSR) or any of the other Institutes/Centers, has the authority to give permission in advance for a late application. Contacting the Division of Receipt and Referral or any other component of the NIH will not lead to either permission to

submit late or an evaluation of the acceptability of the reasons for a delay. Inquiries may be directed to the Division of Receipt and Referral, CSR, NIH, tel.: 301-435-0715; fax: 301-480-1987. Access the Notice, NOT-OD-08-027, at <http://grants.nih.gov/grants/guide>. A list of standard receipt dates is available at <http://grants.nih.gov/grants/funding/submissionschedule.htm>.

Standing NIH Study Section Members Offered Modified Grant Application Procedures

NIH is implementing an alternate plan for submission and review of research grant applications from appointed members of chartered NIH Study Sections to recognize their outstanding service and minimize disincentives to Study Section service. The timing of Study Section meetings and most standard due dates for grant applications overlaps. Thus, reviewers are under pressure to review applications and prepare their own applications simultaneously.

Beginning February 5, 2008, the alternate submission and review procedures described below became available for appointed members of NIH Study Sections. This alternate process is limited to (1) appointed members of chartered standing Study Sections and (2) applications that normally would be received on standard submission dates (but not

special receipt dates). Depending on the timing of the submission and the number of other similar applications received during the premeeting time window, NIH staff will decide if the application will be reviewed in a different standing Study Section or in a Special Emphasis Panel (SEP). These applications will be processed and assigned to NIH Institute Review Offices or CSR Integrated Review Groups (IRGs) using the standard referral guidelines.

The continuous submission process will enable appointed members of chartered NIH Study Sections to submit their applications as soon as they are fully developed. Applications will be reviewed no later than 120 days after receipt. For complete information, refer to the *NIH Guide* Notice, NOT-OD-08-026, available at <http://grants.nih.gov/grants/guide>.

Reminder for NIH Study Section Members: Consult With NIH Program Directors if Planning to Submit Grant Applications With Budgets \geq \$500,000

Despite the alternate submission and review procedures for appointed study section members and ad hoc members (see article above and *NIH Guide* Notice NOT-08-027, <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-027.html>), **the Awaiting Receipt of Application (ARA) process still applies when budget requests are likely to be submitted with direct costs \geq \$500,000 in any given year.** Applicants who are eligible for the alternate grant application submission procedures still must seek agreement from Institute/Center staff to accept assignment prior to the anticipated submission of any application (see *NIH Guide* Notice NOT-OD-02-004 at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-004.html>). Therefore, EGRP recommends that current and prospective grantees who serve on NIH Study Sections con-

tinue to contact EGRP Program Directors well in advance to discuss their submission plans and timelines for grant applications. Contact information for EGRP Program Directors can be obtained at <http://epi.grants.cancer.gov/staff.html>.

Review of Key Web Pages

- NIH Center for Scientific Review News Flash, NIH Gives Chartered Reviewers New Flexibility Submitting Applications: <http://cms.csr.nih.gov/NewsandReports>
- Standard NIH Due Dates for Competing Applications: <http://grants.nih.gov/grants/funding/submissionschedule.htm>

NIH Issues New Application Forms: Relinquishing Grant, Noncompeting Continuation Progress Report

EGRP grantees may wish to take note of two recently revised NIH grant forms:

- *Official Statement Relinquishing Interest and Rights in a PHS Research Grant* (PHS 3734, rev. 11/07). The form is accepted immediately. There are no changes to the data elements or instructions in this revision of the form. Refer to *NIH Guide* Notice, NOT-OD-08-029.
- *Noncompeting Continuation Progress Report for a DHHS Public Health Service Grant* (PHS 2590, rev. 11/07). This form is accepted immediately, and all progress reports received on or after March 1, 2008, MUST use the new instructions and form. Read the instructions carefully. This edition of PHS 2590 implements a number of impor-

tant policy changes, including the NIH Policy for Sharing of Data Obtained in NIH-Supported or Conducted Genome-Wide Association Studies, and registration of clinical trials in <http://clinicaltrials.gov> as required by Public Law 110-85.

One significant change to PHS 2590 is the business process for submission of the continuation progress report. As of March 1, 2008, only the signed original continuation progress report is required to be submitted to the centralized mailing address. (No additional copies are required.) Refer to the *NIH Guide* Notice, NOT-OD-08-030, for further information.

Access the Notices at <http://grants.nih.gov/grants/guide>.

Take Advantage of EGRP's Research Services and Resources

Assistance in Developing Cancer Epidemiology Consortia



Daniela Seminara,
Ph.D., M.P.H.

EGRP facilitates and funds consortia that can conduct the types of large-scale epidemiologic studies needed to address complex questions about the etiology of cancer. The Program provides assistance through all phases of consortia development—from conceptualization through the operation of established consortia. Assistance is provided in numerous ways, including through grant support, assistance

in identifying partners with similar research interests, advice on policies and processes that have proven successful with other cancer epidemiology consortia, participation on steering committees, and in evaluating established consortia.

Daniela Seminara, Ph.D., M.P.H., is EGRP Scientific Consortia Coordinator, e-mail: seminard@mail.nih.gov.

The operating definition used for a Consortium is:

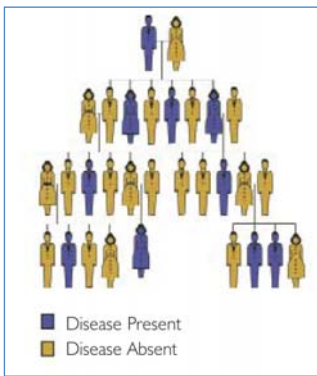
A consortium in epidemiology is a group of scientists from multiple institutions who have agreed to cooperative research efforts involving, but not limited to, pooling of

information from more than one population study for the purpose of combined analyses. The consortium group is able to address scientific questions that cannot otherwise be addressed through the effort of a team of investigators at a single institution due to scope, resources, population size, and need for an interdisciplinary approach. The cooperation usually involves multiple projects over an extended time. Groups participating in a consortium may partner in the writing of research grant applications, but consortia activities are not limited to a specific grant/project.

The creation of a consortium is independent from funding mechanisms and does not indicate definite grant support. However, EGRP and its staff can provide supportive activities and tools.

Learn about the types of assistance available to develop and operate consortia at <http://epi.grants.cancer.gov/Consortia/support.html>. EGRP currently is facilitating and/or funding more than 30 cancer epidemiology consortia. Learn more about them at <http://epi.grants.cancer.gov/Consortia/tablelist.html>.

Breast and Colon Cancer Family Registries (CFRs)

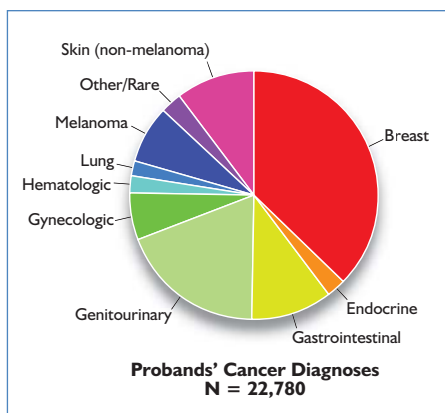


The Breast and Colon Cancer Family Registries (CFRs) are international research infrastructures for investigators interested in conducting population- and clinic-based interdisciplinary studies on the genetic and molecular epidemiology of these cancers and their behavioral implications. A central goal of the CFRs is the translation of this research

to the clinical and prevention setting for the benefit of the Registries' participants and the general public.

The Breast CFR has information and biospecimens contributed by more than 15,300 families across the spectrum of risk for the cancer and from population-based or relative controls. The Colon CFR has information and biospecimens on more than 14,800 families across the spectrum of risk for colon cancer and from population-based or relative controls.

Cancer Genetics Network (CGN)



The Cancer Genetics Network (CGN) is a national network of centers specializing in the study of inherited predisposition to cancer. The resource is available to the research community at large to support studies on the genetic basis

of human cancer susceptibility; integration of this information into medical practice; and behavioral, ethical, and public health issues associated with human genetics.

The database has information on more than 22,000 individuals (16,000 families) with cancer and/or a family history of cancer. Data are available on cancer type, a four-generation cancer family history, genetic testing (if performed), genetic mutation if collected in a CGN special study, any known genetic syndromes in the family, biospecimens on many enrollees in special studies, annual followup on all enrollees, history of tobacco use, and sociodemographic information. More data are available on subsets of enrollees who have

Of particular interest to the CFRs are identification and characterization of cancer susceptibility genes; definition of gene-gene and gene-environment interactions in cancer etiology; and translational, preventive, and behavioral implications of research findings.

Special features of the CFRs include population-based and clinic-based ascertainment, systematic collection of validated family history, epidemiologic risk factor data, clinical and followup data, biospecimens (including tumor blocks and Epstein-Barr Virus-transformed cell lines), and ongoing molecular characterization of the participating families. Researchers who are interested in accessing data and/or biospecimens can learn more about the CFRs and the application process at the CFRs Web site: <http://epi.grants.cancer.gov/CFR>. The CFRs do not provide funding for research.

EGRP Contact: Daniela Seminara, Ph.D., M.P.H., Program Director, Office of the EGRP Associate Director, e-mail: seminard@mail.nih.gov.

participated in CGN special studies. The population enrolled makes possible research on both common and uncommon tumors.

This unique infrastructure enables studies on genes of moderate and low penetrance, as well as more easily identified high-penetrance genes. The CGN welcomes opportunities to collaborate with research groups on important studies, and/or it can provide data and biospecimens—and a range of services and expertise—to support independent studies. Research funding is not provided.

The CGN is operated through a contract awarded by EGRP to Massachusetts General Hospital (MGH) in the spring of 2007. MGH is the Data Coordinating Center and subcontracts with 14 centers that provide the infrastructure to support studies. NCI started the CGN in 1998 through a group of EGRP-funded cooperative agreement grants. Visit the CGN Web site at <http://epi.grants.cancer.gov/CGN>.

Diane M. Finkelstein, Ph.D., is MGH Program Manager/Principal Investigator, and Nora Horick, M.S., is MGH Project Manager.

EGRP Contact: Scott Rogers, M.P.H., Project Officer, EGRP, e-mail: rogerssc@mail.nih.gov.

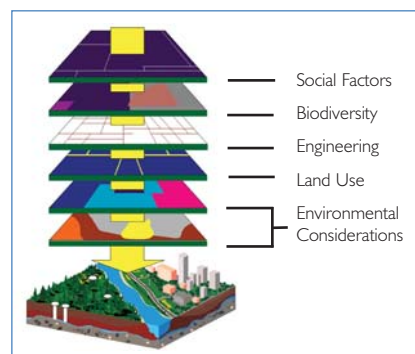
Geographic Information System for Breast Cancer Studies on Long Island (LI GIS)

The Geographic Information System for Breast Cancer Studies on Long Island (LI GIS) is a unique research tool combining an extensive data warehouse with statistical and spatial software and extensions. The LI GIS is designed primarily to study potential relationships between environmental exposures and breast cancer in Nassau and Suffolk counties (Long Island), NY; however, its application can be extended to the study of other diseases.

This unique research tool has more than 80 in-depth, high-quality datasets that primarily cover the 1990s but also cover several previous decades. Breast cancer is a disease of long latency, and data from years ago are especially useful to researchers. The LI GIS incorporates topographic data; demographic data; health outcome data, including relative breast cancer incidence; and environmental data for Long Island. Additional environmental data are included with less detail and geographic precision for areas within 31 miles of the two counties, and very limited data for areas within a 100-mile radius from the midpoint of the boundary line between the two counties. The extended area includes counties in Connecticut, New Jersey, New York, Pennsylvania, Rhode Island, and Massachusetts.

The LI GIS points to a broad range of statistical, analytical, and modeling features that allow users to: calculate, display,

visualize, and compare disease rates; identify disease clusters; conduct spatiotemporal analysis; model potential exposures; and help generate and test hypotheses about possible relationships between a disease and potential exposure. LI



GIS datasets can be applied to base-layer maps, and researchers can use the LI GIS's rich data sources to build on base maps to better understand patterns of environmental exposures and certain determinants of breast cancer or other diseases.

Visit the LI GIS Web site to learn more: <http://li-gis.cancer.gov>. Access other information about the ways in which NCI makes use of GIS technology at <http://gis.cancer.gov>.

Contact: Deborah Winn, Ph.D., Co-Project Officer, EGRP Acting Associate Director, e-mail: winnde@mail.nih.gov.

Visiting Scholars Seminar Series

The EGRP Visiting Scholars Seminar Series brings outstanding scientists in the extramural population sciences community to NCI to share their latest research and facilitates an exchange of ideas on ways to continue moving the science forward. If you are visiting NCI on the day of a seminar, you are welcome to join us.

The following seminars will be held on Mondays from noon to 1 p.m. in Executive Plaza North (EPN), 6130

Executive Boulevard, Conference Room H, Rockville, MD. To obtain a visitor's pass prior to the seminar, contact Leah Sansbury, Ph.D., M.S.P.H., Visiting Scholars Seminar Series Coordinator, and Program Director, Modifiable Risk Factors Branch, tel.: 301-496-9600, e-mail: sansburl@mail.nih.gov.

Refer to the following URL for more information about the series: <http://epi.grants.cancer.gov/visiting/index.html>.

Date and Time	Location	Speaker
December 8, 2008 Noon-1:00 p.m.	Executive Plaza North 6130 Executive Blvd. Conference Room H	John Boice, Jr., Sc.D. Professor, School of Medicine Vanderbilt University Scientific Director International Epidemiology Institute

Date and Time	Location	Speaker
January 12, 2009 Noon–1:00 p.m.	Executive Plaza North 6130 Executive Blvd. Conference Room H	Johanna W. Lampe, Ph.D., R.D. Full Member and Associate Division Director, Cancer Prevention Program, Division of Public Health Sciences Fred Hutchinson Cancer Research Center
February 9, 2009 Noon–1:00 p.m.	Executive Plaza North 6130 Executive Blvd. Conference Room H	Christopher I. Amos, Ph.D. Professor, Department of Epidemiology The University of Texas MD Anderson Cancer Center
March 9, 2009 Noon–1:00 p.m.	Executive Plaza North 6130 Executive Blvd. Conference Room H	Anna R. Giuliano, Ph.D. Chair, Department of Cancer Epidemiology and Genetics Program Leader, Risk Assessment, Detection, and Intervention Program H. Lee Moffitt Cancer Center and Research Institute
April 6, 2009 Noon–1:00 p.m.	Executive Plaza North 6130 Executive Blvd. Conference Room H	(Speaker to be announced.)
May 4, 2009 Noon–1:00 p.m.	Executive Plaza North 6130 Executive Blvd. Conference Room H	(Speaker to be announced.)

Earlier Presentations



Marianne Berwick,
Ph.D., M.P.H.

Marianne Berwick, Ph.D., M.P.H., Associate Director for Population Sciences and Co-Leader of the Population Science Program at the University of New Mexico's Cancer Center, delivered the first 2008-2009 Visiting Scholar Seminar Series presentation at NCI on September 8, 2008, titled "Sun Exposure and Melanoma: A Two-Edged Sword." Dr. Berwick reviewed changes in

melanoma incidence and mortality over time, along with environmental and genetic risk factors for melanoma. She indicated that sun-induced melanomas seem to differ genetically from those that are not sun-induced and are associated with lower mortality rates. Dr. Berwick also discussed recent findings related to associations between an individual's vitamin D status and risk of melanoma.

Dr. Berwick and her colleagues have received EGRP funding to study whether the survival of those diagnosed with melanoma is affected by various risk factors for melanoma. Dr. Berwick, whose laboratory also is investigating DNA repair pathways and vitamin D receptor pathways, closed her presentation by emphasizing the need for greater scientific understanding about the relationship between sun exposure, vitamin D status, and melanoma risk before definitive public health messages regarding sun exposure and vitamin D are developed.



Christine Ambrosone, Ph.D.

Christine B. Ambrosone, Ph.D., Chair of the Roswell Park Cancer Institute's Department of Cancer Prevention and Control, delivered the second 2008-2009 Visiting Scholar Seminar Series presentation at NCI on October 6, titled "Pharmacogenetics and Molecular Epidemiology in a Cooperative Group Setting." In her presentation, Dr. Ambrosone suggested that molecular epidemiology has

helped to open the "black box" for many epidemiologic associations, using the example of breast cancer, genetic variability, and tobacco to illustrate how the blending of subgroups may dilute effects and blur relationships. Dr. Ambrosone also explained that cancer treatments can react differently among individuals and lead to increased or decreased toxicity within the body, which is why an understanding of metabolic pathways and how they differ among individuals is a critical element when treating various cancers.

One of Dr. Ambrosone's current projects is the exploration of antioxidant supplement use, genetic polymorphisms, and outcomes associated with breast cancer chemotherapy. Dr. Ambrosone and colleagues will investigate whether the use of antioxidants has an impact on toxicities as well as overall survival within a therapeutic breast cancer clinical trial.

Abstracts and publications for EGRP-funded research are available at <http://cancercontrol.cancer.gov/grants/query.asp?program=EGRP>.

EGRP at American College of Epidemiology Annual Meeting

EGRP Contributions at 2008 American College of Epidemiology Annual Meeting

In September, several EGRP staff participated in the American College of Epidemiology's Annual Meeting in Tucson, AZ.

Deborah M. Winn, Ph.D., EGRP's Acting Associate Director, moderated a premeeting workshop "Measuring Our Success: Evaluating Impact of Epidemiologic Findings in the Age of Genome-Wide Association Studies." The workshop's speakers included **Daniela Seminara, Ph.D.**, EGRP's Scientific Consortia Coordinator and Program Director; **Emily Harris, O.D.**, Chief of the Translational Genomics Research Branch at the National Institute of Dental and Craniofacial Research; and Dr. Winn.

Recent cancer-related genome-wide association studies (GWAS) were reviewed, along with some unexpected research findings, lessons learned, and future research directions. The workshop also included discussions related to the validation and interpretation of GWAS findings, paradigms for the translation of genomic findings to clinical and/or public health applications, and the need for good risk prediction models.

The speakers all agreed that one of the most vexing challenges associated with GWAS today is achieving an appropriate balance between the timely translation of GWAS findings to clinical and public health applications without doing so prematurely.

Helpful GWAS Resources:

dbGaP (http://www.ncbi.nlm.nih.gov/entrez/query/Gap/gap_tmpl/about.html): The database of Genotype and Phenotype (dbGaP) was developed to archive and distribute the results of studies that have investigated the interaction of genotype and phenotype.

HuGENet (<http://www.cdc.gov/genomics/hugenet/>): Human Genome Epidemiology Network, or HuGENet,™ is a global collaboration of individuals and organizations committed to assessing the impact of human genome variation on population health and how genetic information can be used to improve health and prevent disease.

NIH GWAS Web site (<http://grants.nih.gov/grants/gwas/>): This site contains recent news, data access information, and policy guidance.

Recommendations of the NCI-NHGRI Working Group on Replication in Association Studies: Chanock S, Manolio T, et al. Replicating genotype-phenotype associations. *Nature* 2007; 447: 655-660.

EGRP Staff News

EGRP Program Director Receives NIH Merit Award; Accepts New Position at NCI



Isis Mikhail, M.D.,
M.P.H., Dr.P.H.

Isis Mikhail, M.D., M.P.H., Dr.P.H., Program Director in EGRP's Clinical and Translational Epidemiology Branch, received an NIH Merit Award at the NCI Director's Award Ceremony on November 4, 2008. Dr. Mikhail, and others in NCI's DCCPS and Division of Cancer Epidemiology and Genetics who participate on the NCI Special Studies Institutional Review Board, were recognized for their superior service in developing new

policies for protocol review that address human subject considerations specific to genome-wide association studies. Dr. Mikhail recently accepted the position of Director of the Research Development and Support Program at NCI's Office

of Cancer Complementary and Alternative Medicine (OCCAM).

Dr. Mikhail joined EGRP in 2004. She focused on rare cancers, and organized a May 2007 meeting, sponsored by EGRP and the NIH Office of Rare Diseases (ORD), to stimulate epidemiologic research on rare cancers. Dr. Mikhail also worked with ORD on multiple rare cancer activities, including spinal cord tumors, chordoma, and Merkel cell carcinoma, and developed a funding opportunity announcement for the Rare Diseases Clinical Research Network. In addition, Dr. Mikhail developed a Program Announcement for the development, application, and evaluation of prediction models for cancer risk and prognosis with DCCPS' Applied Research Program and NCI's Division of Cancer Treatment and Diagnosis.

Dr. Mikhail worked with several EGRP-sponsored research consortia, including InterLymph, the International Multiple Myeloma Consortium (IMMC), and Genetic Epidemiology of Melanoma (GEM). In addition, she worked with ORD to help junior investigators obtain funding to travel to consortia

meetings. Dr. Mikhail was very involved with the DCCPS Health Disparities Interest Group and served as co-chair and chair from 2006 to 2008. In this capacity, she helped highlight EGRP-funded epidemiologic research focused on understanding cancer-related health disparities.

Gary Ellison Joins EGRP



Gary Ellison, Ph.D., M.P.H.

Gary L. Ellison, Ph.D., M.P.H., has joined EGRP as an Epidemiologist and Program Director in the Modifiable Risk Factors Branch. Dr. Ellison has published on topics related to cancer epidemiology, surveillance, cancer survivorship, and behavioral methods and has been a journal reviewer and a member of the Small Grants in Cancer Epidemiology (R03) review group.

Before joining EGRP, he was on the faculty of the Department of Family and Community Medicine and Research Coordinator for the Computer-Assisted Telephone Interviewing Research Laboratory at the University of Maryland School of Medicine, where he conducted research in cancer disparities, was a member of the Cancer Research Core for the National Center on Minority Health and Health Disparities (NCMHD)-funded Project Export, and was Principal Investigator for a population-based pilot study of area-level social and economic composition and modifiable cancer risk factors. Dr. Ellison received an NIH research sup-

plement to promote diversity in health-related research and was selected as an NCMHD Health Disparities Loan Repayment Program recipient and a Minority Scholar in Cancer Research by the American Association for Cancer Research.

Dr. Ellison was a member of the Genetic Epidemiology Unit at the National Human Genome Center at Howard University and completed postdoctoral training in 2002 as a Cancer Prevention Fellow at NCI, where he worked with DCCPS' Applied Research Program under Dr. Martin Brown's direction. Under contract with the Centers for Disease Control and Prevention, Dr. Ellison managed the National Program of Cancer Registries-Cancer Surveillance System, which aggregated cancer incidence data and reported annually on the quality, timeliness, and completeness of state registry data. He earned a Ph.D. in epidemiology from the University of South Carolina, where he was an NCI Predoctoral Fellow and Outstanding Epidemiology graduate. Dr. Ellison also holds an M.P.H. from Rollins School of Public Health at Emory University (biostatistics) and a B.S. from The Ohio State University.

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