EGRP Bulletin

Epidemiology and Genetics Research Program

Web Site: 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.

Contents

Summer 2008

New EGRP-Sponsored Funding Opportunities

EGRP sponsors or cosponsors Requests for Applications (RFAs) and Program Announcements (PAs)/Program Announcements with Special Review (PARs). For a full list of funding opportunities, go to *cancercontrol.cancer.gov/funding-apply.html#egrp*.

Mitochondria Research in Cancer Epidemiology, Detection, Diagnosis, and Prognosis

NCI is sponsoring two PAs to stimulate the development and validation of novel mitochondrial (mt) DNA biomarkers for understanding etiology, early detection, diagnosis, prognosis, and risk assessment of cancer, and response to preventive and ameliorative treatment. The PAs invite applications using the Research Project Grant (R01) and the Exploratory/Developmental Grant (R21) funding mechanisms. EGRP is the initiator and a cosponsor of these PAs.

Some of the specific research questions that may be addressed in response to these PAs include but are not limited to:

- Are mitochondrial markers useful for identifying high-risk groups before clinical onset of disease?
- Are mitochondrial characteristics or haplotypes associated with risk of developing cancer? If so, can this help explain racial and ethnic differences in cancer risk?
- Are there modifiable factors or host factors that influence the relationship between mtDNA characteristics and cancer risk?
- Are mitochondria correlated with intermediate disease state in the neoplastic pathway, such as precursor lesions?
- Are genetic and mtDNA alterations (somatic mutations, deletions) correlated during cancer development?
- Can the character of mtDNA anticipate the potential aggressiveness of malignancy?
- How can mitochondrial markers be utilized to predict disease progression and identify novel therapeutic targets?
- Can we advance the technology for high-throughput analysis and imaging of mitochondrial clustering?
- Are there unique mtDNA mutations associated with specific types of cancers?
- How early can mtDNA mutations be detected? Can they be detected in premalignant lesions such as prostate intraepithelial neoplasia (PIN)?
- Can a diagnostic assay based on mutations in mtDNA alone or in combination with other markers be developed for noninvasive detection and/or monitoring of cancer?
- Can nutrition or chemopreventive agents ameliorate genetic effects of mitochondrial activity-induced mutational events?

Because the nature and scope of the proposed research will vary, it is anticipated that the size and duration of each award also will vary. The total project period for R21 applications submitted in response to this funding opportunity announcement (FOA) may not exceed 2 years, and direct costs are limited to $275,000 over the 2-year period, with no more than $200,000 in direct costs allowed in any single year. Standard application submission and receipt dates apply. Both PAs expire on May 8, 2011.

The contact for general questions about epidemiology is EGRP's Mukesh Verma, Ph.D., Chief, Methods and Technologies Branch, and Acting Chief, Host Susceptibility Factors Branch; e-mail: *vermam@mail.nih.gov.*

Also cosponsoring these PAs are NCI's Division of Cancer Prevention (DCP), Division of Cancer Treatment and Diagnosis (DCTD), and the Office of the Director (OD). Please refer to the PAs for the scientific contacts. Access the *NIH Guide for Grants and Contracts* for details:
PA-08-143 (R01): *grants.nih.gov/grants/guide/pa-files/PA-08-143.html*
PA-08-144 (R21): *grants.nih.gov/grants/guide/pa-files/PA-08-144.html*

Other Funding Opportunities of Interest

Rare Diseases Clinical Research Consortia

On behalf of the NIH Office of Rare Diseases (ORD), EGRP announces an RFA for new and renewal cooperative agreement applications (U54) for Rare Diseases Clinical Research Consortia (RDCRC). Proposals are sought for RDCRCs that focus individually on a subset of related rare diseases.

Each RDCRC will consist of a consortium of clinical investigators, institutions, and relevant organizations, including patient support organizations, focused on a subgroup of rare diseases. Support is provided for: (1) collaborative clinical research in rare diseases, including longitudinal studies of individuals with rare diseases, clinical studies, and/or phase I, II, and II/III trials; (2) training of clinical investigators in rare diseases research; (3) pilot and demonstration projects; (4) a test bed for distributed clinical data management that incorporates novel approaches and technologies for data management, data mining, and data sharing across rare diseases, data types, and platforms; and (5) access to information related to rare diseases for basic and clinical researchers, academic and practicing physicians, patients, and the lay public.

Required components of an RDCRC application include:

- A minimum of two clinical research projects (at least one of them must be a longitudinal study);
- A training (career development) component;
- At least one pilot/demonstration project;
- A Web site for educational and research resources in rare diseases;
- Collaboration with patient support organization(s); and
- An administrative unit.

NIH's ORD and participating NIH Institutes and Centers intend to commit approximately $8.75 million in Fiscal Year 2009 to fund up to seven new and/or renewal grant applications for RDCRCs. If additional funds become available, approximately 10 consortia may be funded. An applicant must request a project period of 5 years. In general, budget requests should be limited to $1.25 million in total cost.

Letters of Intent are due July 20, 2008, and applications are due by August 20, 2008.

Contact: Elizabeth Read-Connole, Ph.D., NCI Representative to the Office of Rare Diseases Committee; e-mail: *bconnole@mail.nih.gov*

Access the *NIH Guide for Grants and Contracts* for details:
RFA-08-001 (U54): *grants.nih.gov/grants/guide/rfa-files/RFA-OD-08-001.html*

Biomarkers of Infection-Associated Cancers

NCI and the National Institute of Dental and Craniofacial Research (NIDCR) released funding opportunity announcements (FOAs) using the R01 and R21 mechanisms to identify biomarkers for cancers that are attributable to infectious agents. The goal is to encourage research that will increase knowledge of infectious agent-associated malignancies and use of molecular profiles in early detection, risk assessment, and prevention of cancer.

The objectives of these FOAs are to foster research to increase knowledge of infectious agent-associated malignancies, identify persons at increased risk of developing cancer among infected individuals, and detect early stage cancers in this population. In many cases, the infectious agents are commonly present in humans, but only a small fraction of infected individuals develop cancer. Thus, it is important to identify subpopulations of exposed individuals who are likely to develop cancer and to develop sensitive and specific screening tools to monitor for early stage cancers in infected populations. Molecular markers provide a potential tool to identify the at-risk subpopulation and the presence of early stage cancers. These molecular markers therefore must be able to distinguish ordinary infections per se from infections that contribute to the development of cancer.

Several programmatic areas in need of support for developing molecular signatures for infectious agent-associated cancers are listed below. (This list does not include all possible areas.)

- Molecular profiles of normal, precancerous, and cancerous lesions following infection and of body fluids from infected individuals.

- Evaluation of these molecular profiles for use in gaining a better understanding of the role of infectious agents in cancer development and use in early detection, risk assessment, and prevention of cancer.

Awards issued under these FOAs are contingent on the availability of funds and the submission of a sufficient number of meritorious applications; therefore, the anticipated number of awards is not known. Because the nature and scope of the proposed research will vary from application to application, it is anticipated that the size and duration of each award also will vary. The total amount awarded and the number of awards will depend on the mechanism numbers, quality, duration, and costs of the applications received.

R01 applicants requesting $500,000 or more in direct costs for any year (excluding consortium F&A costs) must carry out the following steps:

(1) Contact the appropriate NIH Institute or Center (IC) program staff member(s) at least 6 weeks before submitting the application, i.e., as plans are being developed for the study;

(2) Obtain agreement from the IC staff member that the IC will accept the application for consideration for award; and

(3) Include a cover letter with the application that identifies the staff member and IC that agreed to accept assignment of the application.

The total project period for R21 applications submitted in response to this funding opportunity may not exceed 2 years. Direct costs are limited to $275,000 over an R21 2-year period, with no more than $200,000 in direct costs allowed in any single year. The R21 is not renewable.

Both FOAs expire May 8, 2011. Standard application submission and receipt dates apply.

NCI's cosponsors for these FOAs include the Division of Cancer Prevention and the Division of Cancer Biology. Please refer to the FOAs for the scientific contacts.

Access the *NIH Guide for Grants and Contracts* for details:
PA-08-156 (R01): *grants.nih.gov/grants/guide/pa-files/PA-08-156.html*, and
PA-08-157 (R21): *grants.nih.gov/grants/guide/pa-files/PA-08-157.html*

Have an Idea for a Research Tool Appropriate for Commercialization? Funding Possible Through a Small Business-Research Partnership


Jay Choudhry, M.S.

Are you a cancer epidemiologist with an idea for a research tool that might be appropriate for commercialization? If so, you may be eligible to obtain funding to pursue your idea through NIH's Small Business Grants Programs. The Small Business Technology Transfer (STTR) Program requires close collaboration between a small business and a research partner at a university or other nonprofit research institution. The small business is to conduct at least 40 percent of the research project, and the single partner research institution conducts at least 30 percent of the work. Funding usually is provided for up to 1 year and $100,000 total cost for phase I feasibility studies, and for up to 2 years and $750,000 for phase II projects.

Assistance in identifying a small business partner (or a research partner) is available via NIH's Small Business Innovation Research (SBIR)/STTR Collaboration Opportunities and Research Partnerships (CORP) Web page at *grants.nih.gov/grants/funding/corp.htm*.

The SBIR, a second program, does not require a research partner. Funding under this program usually is provided for up to 6 months and $100,000 total cost for phase I feasibility studies, and for up to 2 years and $750,000 for phase II projects.

EGRP participates each year in the Omnibus Solicitations for the SBIR and STTR Programs and suggests topics that it is particularly interested in supporting. In the Fiscal Year 2008 Omnibus Solicitations, EGRP expresses interest in supporting:

- Tools for assessment of exposures and biomarkers:
  - MicroRNA profiling in epidemiologic studies.
  - Detection of mitochondrial DNA alterations for cancer epidemiologic studies.
  - Development of methods for measuring biomarkers of human exposure or susceptibility, and of nutritional status, and methods for monitoring changes in biomarkers for use in cancer epidemiologic studies.
  - Development of new or improved devices for quantitative measurement of human exposure to environmental carcinogens for epidemiologic studies.
  - Development of methods to evaluate potential cancer clusters for epidemiologic studies.

- Tools for cancer epidemiology studies:
  - Development of tools to model cancer risks from environmental and occupational agents.
  - Development of software for electronic capture of risk factor data for cancer epidemiologic studies.
  - Development of consumer-friendly risk prediction models from epidemiologic data.
  - Development of software for tracking biological specimens for cancer epidemiologic studies.
  - Development of software for electronic identification, screening, and recruitment of participants, especially minorities, into epidemiologic studies.
  - Development of Web-based data collection or applicable bioinformatics tools for cancer epidemiology, including three focused on rare cancers.
  - Development of software or methods for rapid case ascertainment of cancers.
  - Development of geographic information systems with special visualization techniques for the simultaneous assessment of environmental exposures and health outcomes.
  - Development of tools using publicly available data to identify population-based controls for epidemiologic studies.
  - Development of software for analysis of DNA methylation biomarkers for early detection of prostate or breast cancers with use of specimens from biorepositories.

Access the Omnibus Solicitations from NIH's Small Business Funding Opportunities Home Page at *grants.nih.gov/grants/funding/sbir.htm*.

EGRP Contact: Jay Choudhry, M.S., Program Director, Methods and Technologies Branch, e-mail: *choudhrj@mail.nih.gov*.

The annual **NIH Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR) Programs Conference** is scheduled for July 22–23, 2008, in Atlanta, GA, and will be hosted by the Georgia Tech Enterprise Innovation Institute. Visit the conference Web site at *www.gabio.org/SBIRconference2008*. Jay Choudhry, M.S., will represent EGRP at the conference and will be available for consultations.

NCI Innovative Molecular Analysis Technologies (IMAT) Program RFAs

NCI's Innovative Molecular Analysis Technologies (IMAT) program supports research projects aimed at developing creative methods and tools by which to understand, prevent, diagnose, and treat cancer. It encompasses closely related Requests for Applications (RFAs) in four areas: Innovative Technologies for Molecular Analysis of Cancer, Application of Emerging Technologies for Cancer Research, Innovative Technology Solutions to Cancer Sample Preparation, and Small Business Funding Opportunities. The nine RFAs and the application due dates are listed below.

Cancer epidemiologists may be particularly interested in *Application of Emerging Technologies for Cancer Research* (RFA-CA-08-008), which solicits grant applications proposing exploratory research projects to evaluate the performance of emerging molecular analysis technologies and develop applications for an appropriate cancer-relevant biological system. Specific areas of focus that may be of interest are:

- Technologies suitable for the analysis and characterization of large numbers of samples, including biospecimens, from defined human/patient populations; and
- Technologies for the measurement of exposures to environmental toxicants, pollutants, mutagenic factors, and/or carcinogens.

Announcement	Funding Announcement	Grant Mechanism	Application Due Date
Application of Emerging Technologies for Cancer Research	RFA-CA-08-008	R33	Sept. 24, 2008
Innovative Technologies for Molecular Analysis of Cancer	RFA-CA-08-006	R21	Sept. 24, 2008
Application of Emerging Technologies for Cancer Research	RFA-CA-08-007	R21	Sept. 24, 2008
Innovations in Cancer Sample Preparation	RFA-CA-08-009	R21	Sept. 24, 2008
Innovations in Cancer Sample Preparation	RFA-CA-08-010	R33	Sept. 24, 2008
Innovative Technologies and Applications for the Molecular Analysis of Cancer (SBIR)	RFA-CA-08-011	R43/44	Sept. 24, 2008
Innovative Technologies and Applications for the Molecular Analysis of Cancer (STTR)	RFA-CA-08-012	R41/42	Sept. 24, 2008
Innovations in Cancer Sample Preparation (SBIR)	RFA-CA-08-013	R43/44	Sept. 24, 2008
Innovations in Cancer Sample Preparation (STTR)	RFA-CA-08-014	R41/42	Sept. 24, 2008

R21 = Exploratory/Developmental Research Grant
R33 = Exploratory/Developmental Grants Phase II
R41/42 = Small Business Technology Transfer (STTR) Program Grants
R43/44 = Small Business Innovation Research (SBIR) Program Grants

Visit the IMAT Web site at *imat.cancer.gov* and access the *NIH Guide* Notice, NOT-CA-08-003, at *grants.nih.gov/grants/guide/index.html* to learn more about these funding opportunities.

Take Advantage of EGRP's Research Services and Resources

EGRP invites investigators to use its services and research resources to further cancer epidemiologic research. The Program provides assistance in developing and operating cancer epidemiology consortia and supports three research resources—the Breast and Colon Cancer Family Registries (CFRs), the Cancer Genetics Network (CGN), and the Geographic Information System for Breast Cancer Studies on Long Island (LI GIS), which also can be used for research on other types of cancer and other diseases. Learn more about them below.

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*.

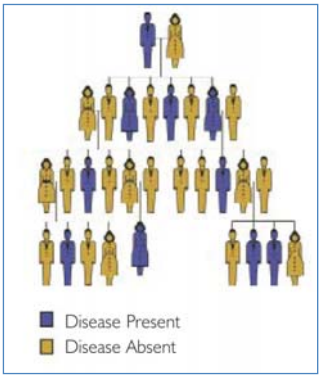
The operating definition used for a Consortium is:

> 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 *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 *epi.grants.cancer.gov/Consortia/table.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.

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: *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*.

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 24,000 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, annual followup on all enrollees, history of tobacco use, and sociodemographic information. More data are available on subsets of enrollees who have 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 fall 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 grants. Visit the CGN Web site at *epi.grants.cancer.gov/CGN*.

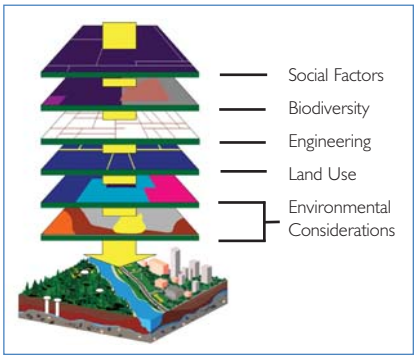
Diane M. Finkelstein, Ph.D., is MGH Program Manager/Principal Investigator, and Nora Horick, M.S., is MGH Project Manager.

EGRP Contact: Carol Kasten, M.D., Project Officer, Clinical and Translational Epidemiology Branch (CTEB), e-mail: *kastenca@mail.nih.gov*.

Long Island Geographic Information System (LI GIS)

The Geographic Information System for Breast Cancer Studies on Long Island (LI GIS) is an enterprise geographic information system combining an Oracle data warehouse, ESRI ArcGIS Suite, and statistical and spatial software and extensions. It is designed to study potential relationships between environmental exposures and breast cancer on Long Island (Suffolk and Nassau counties) and is available to researchers with approved protocols. The LI GIS also can be used to study other diseases.

This unique research tool offers a full suite of GIS software and extensions related to the study of breast cancer. The LI GIS warehouse has more than 80 datasets covering 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 50 kilometers from 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.



Researchers can access the LI GIS remotely or work in its laboratory, located in Reston, VA. There is no fee to use the LI GIS or its laboratory; however, funding for research is not provided. The LI GIS was developed as part of the Long Island Breast Cancer Study Project (LIBCSP). Visit the LI GIS Web site to learn more: *healthgis-li.com*. Access other information about GIS at NCI at *gis.cancer.gov*.

Contact: Shannon Lynch, M.P.H., Co-Project Officer, Office of the EGRP Associate Director, e-mail: *lynchs@mail.nih.gov*.

Get Step-by-Step Help on Preparing Progress Reports and Final Reports for EGRP

DCCPS has developed two new Web pages with brief step-by-step instructions to help in preparing Progress Report Summaries and Final Reports for EGRP and other components of the Division. Principal Investigators supported through EGRP and their staffs should find these instructions helpful:

- Main DCCPS Grant Application Help Page: *cancercontrol.cancer.gov/funding_info.html*
- Step-by-Step Help on Completing Progress Reports: *cancercontrol.cancer.gov/help-2590.html*
- Step-by-Step Help for Final Reports: *cancercontrol.cancer.gov/help-2590-fr.html*
- NIH Announces New Centralized Processing Center for Receipt of Grant Closeout Documents: *grants.nih.gov/grants/guide/notice-files/NOT-OD-08-061.html*

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 the 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 *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 *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.

NIH Revised Policy Issued on Enhancing Public Access to Archived Publications

The NIH Public Access Policy first was implemented in 2005, and compliance was voluntary. In January 2008, the policy was revised to require that, as of April 7, 2008, all final peer-reviewed manuscripts arising from NIH funds must be submitted to PubMed Central (PMC, *pubmedcentral.nih.gov*) on acceptance for publication. PMC is a free digital archive of full-text, peer-reviewed journal articles that is managed by NIH's National Library of Medicine (NLM). Furthermore, 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: *publicaccess.nih.gov/index.htm*
- Frequently Asked Questions: *publicaccess.nih.gov/FAQ.htm#content*
- Communications and Training: *publicaccess.nih.gov/communications.htm*
- *NIH Guide* Notice, NOT-OD-08-033: *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 *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 *grants.nih.gov/grants/guide*. A list of standard receipt dates is available at *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 to 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 *grants.nih.gov/grants/guide*.

Reminder for NIH Study Section Members: Consult With NIH Program Directors if Planning to Submit Grant Applications With Budgets ≥ $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, *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 ≥$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 *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 continue 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 *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: *cms.csr.nih.gov/NewsandReports*
- Standard NIH Due Dates for Competing Applications: *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 important 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 *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 *grants.nih.gov/grants/guide*.

New e-Tools

Colorectal Cancer Mortality Projections. NCI's Cancer Intervention and Surveillance Modeling Network (CISNET) developed this Web site (*cisnet.cancer.gov/projections/colorectal*) to help cancer control planners, program staff, and policymakers consider the impact of risk factor reduction, increased early detection, and increased access to optimal treatment on future colorectal cancer mortality rates.

This site shows the results of simulation modeling—computer simulations of colorectal disease progression in a population with the characteristics of the U.S. population. Use this information to:

- See how **policy** options to increase cancer prevention, screening, and access to state-of-the-science treatment can affect future mortality trends;
- Help determine **cancer control program** priority areas for new intervention investments; and
- Identify **research** questions and opportunities.

Cancer Trends Progress Report: 2007 Update. This report, which spans the cancer control continuum from prevention through end of life, summarizes our nation's progress against cancer in relation to the Healthy People 2010 targets developed by the U.S. Department of Health and Human Services (HHS). This online report, first issued in 2001 as the *Cancer Progress Report*, is released every other year. The report, intended for policymakers, researchers, clinicians, and public health service providers, offers updated national trends data in a user-friendly format. Report features include:

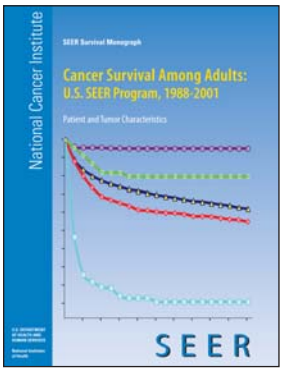
- Quick tutorial to ease navigation and downloading of materials within the report
- Updated "Trends-at-a-Glance" snapshot
- Links to NCI's State Cancer Profiles' state- and county-level data
- Links to colorectal cancer mortality projections
- Links to Healthy People 2010 materials
- Data, graphs, and slides that are easy to download
- Custom report features
- Open text search capability
- Fully accessible to persons with disabilities

The report can be viewed online at *progressreport.cancer.gov*.

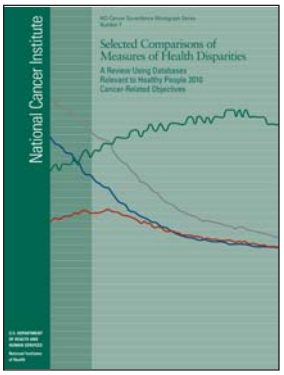
New Publications

Coming October 2008

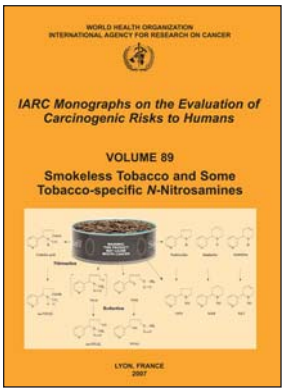
Cancer Epidemiology, Volumes 1 and 2. Population studies and epidemiology facilitate the discovery of genetic, epigenetic, and environmental determinants of cancer and the development of new approaches to cancer control and prevention; as a result, they play a central role in the creation of health policies. *Cancer Epidemiology,* available October 8, 2008, explores areas of research that cover etiologic factors or determinants that contribute to the development of cancer and describes the latest technologies in cancer epidemiology. In *Volume 1, Host Susceptibility Factors*, leading experts provide chapters on cancer incidence, prevalence, mortality, surveillance, methods, technologies, study design, and host susceptibility factors in cancer epidemiology. In *Volume 2, Modifiable Factors*, leading experts provide chapters on modifiable factors in cancer epidemiology, epidemiology of organ-specific cancer, and environmental and lifestyle factors. This two-volume series, part of the *Methods in Molecular Biology*™ series by Humana Press, is edited by Mukesh Verma, Ph.D., Chief, EGRP Methods and Technologies Branch and Acting Chief, Host Susceptibility Factors Branch. Information about these publications is available at *springer.com*.



SEER Survival Monograph. Cancer Survival Among Adults: U.S. SEER Program, 1988-2001. Patient and Tumor Characteristics. NCI's Surveillance, Epidemiology, and End Results (SEER) Program developed this monograph to examine cancer survival by patient and tumor characteristics for more than 1.6 million adult cancers diagnosed during the period 1988–2001. The patient characteristics include age, race, and sex; tumor characteristics include subsite, size and extension of the tumor, lymph nodes positive, distant metastases, and histologic type. The report uses survival data from the SEER Program, currently the only source of statistics on cancer survival by stage in the United States. Each chapter covers a distinct anatomical site and associated histologies. The descriptive analyses on cancer survival rates presented by this monograph will inform health professionals, especially those who are concerned about cancer prognosis. To view, print, or order a copy of this monograph, visit *seer.cancer.gov/publications/survival*.



Selected Comparisons of Measures of Health Disparities: A Review Using Databases Relevant to Healthy People 2010 Cancer-Related Objectives. This report uses case studies to analyze the performance and appropriateness of various potential measures of health disparities. It complements a previous monograph, *Methods for Measuring Cancer Disparities: Using Data Relevant to Healthy People 2010 Cancer-Related Objectives,* which evaluated measures of disparity on theoretical grounds. The current monograph presents results from 22 separate analyses in 10 case studies and includes assessments of socioeconomic, race, ethnic, and geographic disparities in a range of cancer-related outcomes, such as mortality, incidence, risk factors, and screening. Overall, the report demonstrates that the choice of particular methods for measuring health disparities makes a substantive difference in the results and interpretation of data. To view, print, or order a copy of this monograph when it is released, visit *seer.cancer.gov/publications*.



IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, Volume 89: Smokeless Tobacco and Some Tobacco-specific *N*-Nitrosamines. This volume from the International Agency for Cancer Research (IARC) contains monographs on smokeless tobacco and some tobacco-specific *N*-Nitrosamines. It describes smokeless tobacco practices, reviews studies of cancer in humans and in experimental animals related to smokeless tobacco products and tobacco-specific *N*-nitrosamines, as well as other data relevant to carcinogenicity and its mechanisms. Several scientists from EGRP's Division of Cancer Control and Population Sciences (DCCPS) participated in preparation of the monographs: Deborah (Debbie) Winn, Ph.D., EGRP Acting Associate Director; Cathy Backinger, Ph.D., M.P.H., Chief, Tobacco Control Research Branch (TCRB); and Mirjana Djordjevic, Ph.D., TCRB, Behavioral Research Program (BRP). The volume can be viewed at *monographs.iarc.fr*.

Britt Reid and Mukesh Verma Appointed Branch Chiefs

EGRP has two new Branch Chiefs: **Britt Reid, D.D.S., Ph.D.,** has been named to head the Modifiable Risk Factors Branch (MRFB), and **Mukesh Verma, Ph.D.**, has been named to head the Methods and Technologies Branch (MTB). These positions were established last year when EGRP reorganized and changed from a two- to a four-branch structure.

Britt Reid, D.D.S., Ph.D.

Dr. Reid came to NCI in 2007 as a Program Director in the Modifiable Risk Factors Branch (MRFB). Prior to joining EGRP, he was an Assistant Professor in the Department of Health Promotion and Policy at the University of Maryland Dental School, where he was director of the graduate course Applied Scientific Evidence, an epidemiology consultant for the NIH-funded Data Resource Center, and global data director for the Special Olympics oral health program. Dr. Reid also was a Principal Investigator for two NIH-funded grants addressing head and neck cancers and co-Investigator for two additional NIH-funded grants addressing the impact of comorbid conditions on health outcomes. He served as a reviewer of epidemiology and cancer content for seven scientific journals and two NIH Study Sections, and he has authored or coauthored 27 manuscripts in peer-reviewed scientific journals since the year 2000.

Prior to his academic career, Dr. Reid practiced clinical dentistry in Washington, DC, and as a Naval Officer in support of the Fleet Marine Force in Japan. He received his D.D.S. from the University of Michigan and Ph.D. in epidemiology from The Johns Hopkins Bloomberg School of Public Health.

MRFB focuses on supporting and stimulating research on cancer factors that may be modifiable, such as diet and nutrition, alcohol, physical activity and energy balance, tobacco, infectious diseases, physical and chemical agents, and medical exposures.

Mukesh Verma, Ph.D.

Dr. Verma joined EGRP as a Program Director in 2004. In 2005, he was appointed Acting Chief of the former Analytic Epidemiology Research Branch (AERB). When EGRP reorganized, Dr. Verma was appointed Acting Chief of both the Methods and Technologies Branch (MTB) and the Host Susceptibility Factors Branch (HSFB). He continues to serve as Acting Chief of HSFB.

Dr. Verma is responsible for developing EGRP's initiative to stimulate research on epigenetic approaches in cancer epidemiology and has been instrumental in developing epigenetic research for NIH as a whole. He helped to develop an RFA on *Environmental Influences on Epigenetics* with the National Institute of Environmental Health Sciences (NIEHS) and represents the Division of Cancer Control and Population Sciences (DCCPS), of which EGRP is a part, in NIH's Roadmap Initiative on epigenetics.

He is known within the extramural research community as an EGRP Program Director for PAs on *Small Grants for Cancer Epidemiology* and *Pilot Studies in Pancreatic Cancer*, and is a co-Program Director for initiatives in gene-environment interactions in cancer etiology. He was, and continues to be, a co-Program Director for initiatives in gene-environment interactions in cancer etiology, including the Breast and Prostate Cancer Cohort Consortium (BPC3), which is a collaborative project to pool data and biospecimens from a group of large prospective cancer epidemiology cohorts. He also organized a workshop to explore developing a concept for a research initiative on mitochondrial DNA and cancer epidemiology.

Before joining EGRP, Dr. Verma was a Program Director in NCI's Division of Cancer Prevention (DCP), where he worked in the areas of biomarkers, early detection, risk assessment, and prevention. He also was Coordinator of DCP's SBIR and STTR Programs. Dr. Verma holds an M.Sc. from Pantnagar University, a Ph.D. in the field of host-virus interaction from Banaras Hindu University, and did postdoctoral research at George Washington University.

MTB focuses on developing and improving methods for epidemiologic data collection, study design, and analysis; on modifying approaches developed in the context of other research endeavors for cancer epidemiologic settings; and on methods to increase understanding of cancer susceptibility. The Branch also manages EGRP's SBIR/STTR Programs. Additional information about EGRP's reorganization is available at *epi.grants.cancer.gov/reorganize.html*.

Other EGRP Staff News

Elizabeth Gillanders, Ph.D.

Elizabeth (Liz) Gillanders, Ph.D., has joined EGRP as a Program Director in its Host Susceptibility Factors Branch (HSFB) from the National Human Genome Research Institute (NHGRI). At NHGRI, she was a senior research fellow and earlier headed its Genetic Epidemiology Unit within the Cancer Genetics Branch. Her research at NHGRI centered on family-based studies of cancer susceptibility, with an emphasis on melanoma, prostate cancer, and breast cancer. Recently, Dr. Gillanders has been involved in a genome-wide association study of melanoma supported by a Research Training Fellowship in the genetic epidemiology of the cancer.

Dr. Gillanders received her B.A. from The College of William and Mary; B.S. in Molecular Genetics from The Johns Hopkins University; and Ph.D. in Genetic Epidemiology from The Johns Hopkins Bloomberg School of Public Health, where she investigated genetic factors contributing to melanoma susceptibility. She is an Adjunct Assistant Professor at The Johns Hopkins Bloomberg School of Public Health, where she teaches an introductory human genetics course.

Christiine Kaefer, M.B.A., R.D.

Christine (Christie) Kaefer, M.B.A., R.D., is EGRP's new Communications Coordinator and will be writing and disseminating information about NCI and the Program for investigators working in the field of cancer epidemiology. Prior to joining EGRP, Ms. Kaefer was a Scientific Information Analyst in NCI's Office of Centers, Training, and Resources (OCTR), where she assisted the Cancer Centers Branch with communications activities related to NCI-designated Cancer Centers. Ms. Kaefer first joined NCI in 2005 as a Presidential Management Fellow (PMF) after completing her M.B.A. at Virginia Tech. As a PMF, she developed communications materials for DCCPS' Behavioral Research Program (BRP), co-authored publications with the Division of Cancer Prevention's (DCP) Nutritional Sciences Research Group, and reviewed nutrition education materials for the U.S. Department of Health and Human Services' (HHS) Office of Disease Prevention and Health Promotion.

In addition, Ms. Kaefer is a Registered Dietitian, has a B.S. in Nutritional Sciences from Cornell University, and completed a dietetic internship at Walter Reed Army Medical Center. For 8 years, she served on Active Duty in the U.S. Army in a variety of clinical and management roles.

Adrienne Overton

Adrienne Overton has joined EGRP as a Program Analyst in MTB. She comes to EGRP from the NIH Clinical Center Department of Anesthesia and Surgical Services. For the past 10 years, she has held various administrative positions in the medical field. Ms. Overton holds a B.S. in Health Care Management from Potomac College, Washington, DC, and is near completion of her work to obtain an M.P.A. in Health Services from Walden University, Baltimore, MD.

Damali Martin, Ph.D., M.P.H.

Damali Martin, Ph.D., M.P.H., has joined EGRP as an NCI Cancer Prevention Fellow. She is learning the responsibilities of a Program Director under the direction of Isis Mikhail, M.D., M.P.H., Dr.P.H., Clinical and Translational Epidemiology Branch (CTEB).

NCI's Cancer Prevention Fellowship Program (CPFP) provides postdoctoral training opportunities in cancer prevention and control, including training toward an M.P.H. degree. Dr. Martin holds a Ph.D. in Cell Biology and Molecular Genetics from the University of Maryland at College Park. She received an M.P.H. in Epidemiology and Biostatistics from The Johns Hopkins Bloomberg School of Public Health, where she investigated human papillomavirus (HPV) viral load and its association with stage of cervical neoplasia.

Through the CPFP, Dr. Martin has worked in the Breast and Prostate Study Group in the Laboratory of Human Carcinogenesis, NCI Center for Cancer Research. Her research focused primarily on studying the association between DNA polymorphisms and risk for breast cancer, and molecular epidemiology related to the study of health disparities.

Epidemiology and Genetics Research Program (EGRP) Staff

Epidemiology and Genetics Research Program
Telephone: 301-496-9600; Fax: 301-435-6609
Web site: *epi.grants.cancer.gov*

Office of the Associate Director
Deborah M. Winn, Ph.D., EGRP Acting Associate Director
Diane Horn-Cruder, Program Analyst
Christie Kaefer, M.B.A., R.D., Communications Coordinator
Shannon Lynch, M.P.H., Program Analyst
Scott Rogers, M.P.H., Program Analyst
Daniela Seminara, Ph.D., M.P.H., Scientific Consortia Coordinator and Program Director

Host Susceptibility Factors Branch
Mukesh Verma, Ph.D., Acting Chief
Elizabeth (Liz) M. Gillanders, Ph.D., Program Director
Sheri Dixon Schully, Ph.D., Program Director

Modifiable Risk Factors Branch
Britt C. Reid, D.D.S., Ph.D., Chief
Chinonye (Nonye) Harvey, M.P.H., Program Analyst
Leah Sansbury, Ph.D., M.S.P.H., Program Director
Vaurice Starks, Program Director

Methods and Technologies Branch
Mukesh Verma, Ph.D., Chief
Jay Choudhry, M.S., Program Director
Adrienne Overton, Program Analyst

Clinical and Translational Epidemiology Branch
Deborah M. Winn, Ph.D., Acting Chief
Carol Kasten, M.D., Medical Officer, Geneticist, and Project Officer
Damali Martin, Ph.D., Cancer Prevention Fellow
Isis S. Mikhail, M.D., M.P.H., Dr.P.H., Program Director

Sources of Information on Grant Policies and Funding

- Our NCI Division of Cancer Control and Population Sciences (DCCPS) Home page: *cancercontrol.cancer.gov* for grant policy alerts and information on funding opportunities.
- NCI Division of Extramural Activities (DEA): *deainfo.nci.nih.gov*
- *Grants.gov* (central resource to find and apply for U.S. grants)
- Research Resources
  - NCI directory of more than 175 products: *resresources.nci.nih.gov*
  - DCCPS Public Use Data Sets: *cancercontrol.cancer.gov/cr-dataset.html*
- Subscribe to:
  - NCI Cancer Bulletin (bi-weekly newsletter): *cancer.gov/ncicancerbulletin*
  - NIH Guide for Grants and Contracts: *grants.nih.gov/grants/guide/listserv.htm*
  - NIH Inside eRA for Partners (Electronic Research Administration or "The Commons") (occasional updates): *era.nih.gov/eranews*
  - NIH Extramural Nexus (bimonthly newsletter for grantees): *grants.nih.gov/grants/nexus.htm*
  - EGRP's Listserv (occasional Bulletins, News Flashes) contact: *kaeferc@mail.nih.gov*
- **Everything you wanted to know about the NCI Grants Process...but were afraid to ask** (2005). Access online at *www.cancer.gov/admin/gab* or order a print copy via NCI's online Publications Locator: *https://cissecure.nci.nih.gov/ncipubs*. **(The publication does not include information about NIH's mandatory transition to electronic submission of applications and the new form; see *era.nih.gov/ElectronicReceipt/index.htm*.)**

Epidemiology and Genetics Research Program
Division of Cancer Control and Population Sciences
National Cancer Institute
6130 Executive Boulevard, Room 5113, MSC 7395, Bethesda, MD 20892-7395
Telephone: 301-496-9600; Fax: 301-435-6609