AMERICAN CANCER SOCIETY

POSTDOCTORAL FELLOWSHIP

POLICIES AND INSTRUCTIONS

EFFECTIVE JANUARY 2011

AMERICAN CANCER SOCIETY, INC. National Home Office Extramural Grants Department 250 Williams Street, NW, 6th Floor Atlanta, GA 30303-1002

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PLEASE NOTE:

Both the electronic and paper copies of the completed application must arrive at the American Cancer Society Extramural Grants Office by 5pm eastern time on the stated deadline date.

MISSION

The American Cancer Society is the nationwide, community-based, voluntary health organization dedicated to eliminating cancer as a major health problem by preventing cancer, saving lives and diminishing suffering from cancer through research, education, advocacy, and service.

POSTDOCTORAL FELLOWSHIP POLICIES CONTENTS

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1. OVERVIEW OF THE EXTRAMURAL RESEARCH AND TRAINING GRANTS PROGRAM OF THE AMERICAN CANCER SOCIETY

With a primary focus on beginning investigators, the American Cancer Society's Extramural Grants Program seeks to support and promote high impact and innovative cancer research across a wide range of disciplines to meet critically important needs in the control of cancer.

Each year, the Society receives approximately 2,000 requests for research funding and health care professional training support. All proposals are subjected to multiple levels of peer review to identify the most meritorious and innovative projects for funding.

The Society offers extramural support for research and training via the programs described below. For program specific information, please see Section 19.

GRANT PROGRAMS

HEALTH PROFESSIONAL TRAINING IN CANCER CONTROL – Virginia Krawiec, MPA, Program Director

Grants in support of nurses, physicians and social workers to pursue training in outstanding programs that must meet high standards for excellence. The immediate goal is to encourage highly qualified individuals to enter careers in cancer prevention and control practice. The program goal is to accelerate the application of research findings in cancer prevention and control by increasing the number of nursing and social work clinicians and researchers with expertise in and career commitment to cancer control, and generalist physicians actively engaged in cancer control.

MOLECULAR GENETICS & BIOCHEMISTRY OF CANCER PROGRAM – Michael

Melner, PhD, Program Director

This program focuses on the genes involved in cancer and how alterations in those genes (mutations, deletions, and amplifications) play roles in the process. Also of interest is the examination of the molecules involved in cancer (proteins, nucleic acids, lipids, and carbohydrates) and how alterations in those molecules affect the disease. The program highlights potential targets for new treatments of cancer and attacking the signaling mechanisms which control the disease.

CANCER CELL BIOLOGY AND METASTASIS – Charles Saxe, PhD, Program Director The primary goal of this program is to provide an understanding of the nature of cancer cells so they can be more effectively treated and eliminated. Emphases include understanding the fundamental controls of normal and cancer cells with a focus on how cells regulate when to grow, when to divide and when to die; how cells create an identity and how cells relate to the local environment and to other cells; how cells regulate when and how to move from one site to another. To most completely reach the program goal a wide variety of cells are utilized so all aspects of cell biology can be examined.

PRECLINICAL AND TRANSLATIONAL CANCER RESEARCH – William Phelps, PhD, Dragman Director

Program Director This program focuses at the interface between laboratory investigations and human testing. The scope of the program includes investigations of the role of infectious diseases in cancer, the synthesis and discovery of cancer drugs, the creation and use of animal models of cancer, and the role of individual or groups of genes in different types of cancer.

CLINICAL CANCER RESEARCH AND IMMUNOLOGY - William H. Chambers, PhD,

Program Director

Focus on increasing clinical research derived from advances in basic and epidemiologic research. Pursue clinical trials of new imaging agents and modalities monitoring cancer development, progression and response to therapy. Improve understanding of cancer-related inflammatory responses, immunosurveillance and immunotherapy. Increased use of the immune system for cancer prevention. Integration of immunotherapy into combination therapies for cancer. Increased fundamental knowledge of the effects of the environment and nutrition on cancer prevention, initiation and progression.

CANCER CONTROL AND PREVENTION RESEARCH – Ronit Elk, PhD, Program Director

Study of behaviors (of individuals or health care professionals or health care systems), or interventions in changing these behaviors or systems, resulting in either a reduction in cancer risk, enhancement in detecting it early, better informed treatment decision-making, or improvement in the quality of life of patients and families. Special emphasis is placed on reducing disparities in disadvantaged groups.

GRANT MECHANISMS

RESEARCH GRANTS FOR INDEPENDENT INVESTIGATORS

Research Scholar Grants—provide the resources for investigator-initiated research in a variety of cancer-relevant areas. Applicants must be independent, self-directed researchers within six years of their first academic appointment. The maximum award is for 4 years and for as much as \$200,000 per year (direct costs), plus 20% allowable indirect costs.

The only exception is in the Priority Program in Cancer Control: research studies in psychosocial, behavioral, health policy or health services research studies that address cancer health disparities. In this case, investigators can be at any stage of their career. A further exception are applications in **population-based** psychosocial or behavioral studies; awards up to a maximum of 5 years and \$400,000 per year (direct costs), plus 20% allowable indirect costs.

Institutional Research Grants—Awarded to institutions as block grants to provide seed money for newly independent investigators to initiate research projects. Grants are made for one to three years, and average \$120,000 per year. These grants are renewable.

MENTORED TRAINING AND CAREER DEVELOPMENT GRANTS

Postdoctoral Fellowships—Support for the training of researchers who have received a doctoral degree to provide initial funding leading to an independent career in cancer research (including basic, preclinical, clinical, cancer control, psychosocial, behavioral, epidemiology, health services and health policy research). Awards may be for three years with progressive stipends of \$44,000, \$46,000, and \$48,000 per year, plus a \$4,000 per year fellowship allowance. Depending on availability of special endowment funds, the Society annually selects one or more of the top-ranked fellowships to be supplemented above the standard stipend. During the second or third year of the award, ACS Postdoctoral Fellows will be invited to attend a Fellows Symposium to present their work, meet with senior leaders in cancer research, and develop additional professional skills important in their transition to independent research careers.

Mentored Research Scholar Grants in Applied and Clinical Research—Provides support for mentored research and training to full-time junior faculty, typically within the initial four years of their first independent appointment. The goal is for these beginning investigators to become independent researchers as either clinician scientists or cancer control and prevention researchers. Awards are for up to five years and for up to \$135,000 per year (direct costs), plus 8% allowable indirect costs. A maximum of \$10,000 per year for the mentor(s) (regardless of the number of mentors) is included in the \$135,000.

Cancer Control Career Development Awards for Primary Care Physicians— Support for primary care physicians in supervised programs intended to develop clinical and teaching expertise and the capacity to perform independent research or educational innovation in cancer control. Awards are for 3 years and for up to \$100,000 per year. A maximum of \$10,000 per year for the mentor(s) may be included in the budget.

Physician Training Awards in Cancer Prevention—Awards to institutions to support physician training in accredited preventive medicine residency programs that provide cancer prevention and control research and practice opportunities. Awards are for four years in the total amount of \$300,000, based on an average of \$50,000 per resident training year. These grants are renewable.

PREDOCTORAL TRAINING

Doctoral Training Grants in Oncology Social Work—Awards to doctoral students to conduct research. Initial 2-year grant providing a stipend of \$20,000 per year with possibility of a 2-year competitive renewal.

Master's Training Grants in Clinical Oncology Social Work—Awards to institutions to support the training of second-year master's degree students to provide psychosocial services to persons with cancer and their families. Awards are for one year in the amount of \$12,000 (trainee stipend of \$10,000, and \$2,000 for faculty professional development). These grants are renewable.

Doctoral Degree Scholarships in Cancer Nursing—Provide support for study in a doctoral degree program in nursing or a related area, and prepare the graduate for a career as a cancer nurse scientist. The initial award is for two years and provides a stipend of \$15,000 per year. Scholarships may be renewed for an additional two years based on satisfactory progress.

Graduate Scholarships in Cancer Nursing Practice —Support for graduate students pursuing a master's degree in cancer nursing or doctorate of nursing practice (DNP). Awards may be for two years with stipend of \$10,000 per year.

PROFESSOR AWARDS

Research Professor Awards—Awarded to outstanding mid-career investigators who have made seminal contributions that have changed the direction of cancer research. In general, applicants will recently have attained the rank of full professor. The awards are for 5 years in the total amount of \$400,000, and may be renewed once.

Clinical Research Professor Awards —Awarded to outstanding mid-career investigators who have made seminal contributions in areas of cancer control that have changed the direction of clinical, psychosocial, behavioral, health policy or epidemiologic cancer research. In general, applicants will recently have attained the rank of full professor. The awards are for 5 years in the total amount of \$400,000, and may be renewed once.

INTERNATIONAL PROGRAMS

Audrey Meyer Mars International Fellowships in Clinical Oncology—Support for one year of advanced training in clinical oncology at participating US cancer centers to qualified physicians and surgeons from other countries, particularly countries where advanced training is not readily available. This program is limited to non-US citizens and provides up to \$40,000 annually. SUSPENDED

American Cancer Society - UICC International Fellowships for Beginning Investigators— One-year fellowships of up to \$45,000 funded by the American Cancer Society to advance the academic career development of beginning cancer investigators from low-, lower-middle- and upper-middle-income countries as defined by the World Bank. Funding preference will be given to applicants who propose to conduct translational, clinical, epidemiologic, psychosocial, behavioral, health services or health policy research. Application forms may be obtained from the UICC Fellowship Department at <u>http://fellows.uicc.org/</u>

NEW INITIATIVES

Priority Program in Cancer Health Disparities Research

The American Cancer Society is committed to reducing cancer health disparities and has set strategic priorities for eliminating such disparities through research, education, advocacy, and service. The Society has set as a nationwide objective the goal of eliminating disparities in cancer burdens by 2015. To achieve this goal, the Extramural Research and Training Grants (EG) Department has made the reduction of cancer health disparities a priority area of focus for

the Cancer Control and Prevention Research Program with a call for applications in psychosocial and behavioral research and in health policy and health services research that address cancer health disparities.

Applications will be accepted using one of four mechanisms: Postdoctoral Fellowship, Mentored Research Scholar Grant, Research Scholar Grant, or Clinical Research Professor. Annual deadlines: April 1 and October 15.

REQUESTS FOR APPLICATIONS (RFAS)

Pilot and Exploratory Projects in Palliative Care of Cancer Patients and their Families — Supports investigators performing pilot and exploratory research studies that test interventions, develop research methodologies, and explore novel areas of research in palliative care of cancer patients and their families. Applications will be accepted via the Pilot and Exploratory Grants Mechanism. The maximum award is for 2 years and up to \$60,000 per year (direct costs) plus 20% indirect costs. It is anticipated that a total of \$500,000 will be available to fund 5 to 7 grants. Annual Deadline: October 15

Research Scholar Grant in the Role of Healthcare and Insurance in Improving Outcomes in Cancer Prevention, Early Detection and Treatment—Supports projects that investigate how healthcare costs, healthcare system structure and capacity, socioeconomic factors (including insurance status), personal characteristics (such as race and ethnicity), and delivery of healthcare services affect outcomes related to cancer prevention, early detection, and treatment. The purpose is to stimulate research on the effects of the US healthcare system structure and the role of insurance on access to screenings and treatment. Applications will be accepted via the Research Scholar Grant in Cancer Control and Prevention award mechanism. The maximum award is for 4 years and up to \$200,000 per year (direct costs) plus 20% indirect costs.

MEN2 Thyroid Cancer Consortium - The American Cancer Society announces a **Request for Applications** for the **American Cancer Society MEN2 Thyroid Cancer Consortium**. Up to seven (7) **Research Scholar** and/or **Mentored Research Scholar** grants and up to five (5) **Postdoctoral Fellow** grants will be awarded. The Consortium will be led by a single renowned senior scientist who will be awarded the American Cancer Society **MEN2 Thyroid Cancer Professorship** and act as leader for the overall program. Appropriate areas of investigation include, but are not limited to: understanding consequences of *RET* mutations, molecular events underlying the development of MEN2-related tumors, improved animal models of MEN2, new screening and monitoring tools, new imaging approaches, and new pharmacologic and other strategies to blunt the effects of mutations in *RET* and other genes associated with medullary thyroid cancer. Annual deadlines: April 1 and October 15.

Postdoctoral Fellowship Awards in the Early Detection of Cancer - Canary Foundation, in partnership with the American Cancer Society, is extending its postdoctoral fellowship program focused on studies towards development of strategies for the early detection of cancer. Research should be directed at new approaches to improve clinical methods for the screening of primary tumors and/or metastases. Awards will be 3 years with stipends of \$44,000, \$46,000, and \$48,000 per year, plus an annual \$4,000 fellowship allowance. Based upon availability of funds

and scientific merit of the applications, it is anticipated that up to 2 awards will be made. To restrict funding to full 3 year fellowships, applicants may at the time of application, have had no more than 2 years of research experience beyond their terminal degree (MD or PhD excluding clinical service). Applicants must be US citizens or permanent residents working with an accomplished mentor at a non-profit institution. Deadline: October 15

2. AUTHORITY FOR MAKING GRANTS

All American Cancer Society grants and awards are made by the Chief Executive Officer on behalf of the Society's Board of Directors.

3. SOURCE OF FUNDS

The American Cancer Society obtains its funds principally from public donations collected annually by our three million volunteers. In order to disseminate information about the Society's Extramural Research and Training Grants Program to our volunteers and to the public, grantees may occasionally be asked to give brief presentations to professional and lay audiences.

4. WHO MAY APPLY

Applicants for American Cancer Society grants and awards must at the time of application be United States citizens, noncitizen nationals, or permanent residents of the United States. Permanent residents must submit with the application notarized evidence indicating that they have a Resident Alien Card or "Green Card" (I-551) or have been approved for the issuance of such card as evidenced by an official passport stamp of the United States Immigration Service or a form I-797 Notice of Action which indicates that the application for permanent residence has been approved. Non-citizen nationals are persons who, although not US citizens, owe permanent allegiance to the United States. They are generally persons born in outlying US possessions (e.g., American Samoa and Swains Island).

The Society's grants and awards are made to not-for-profit institutions located within the United States, its territories, and the Commonwealth of Puerto Rico. A not-for-profit institution is one that –IF REQUESTED- can provide:

- A current letter from the Internal Revenue Service conferring 501(c)(3) status,
- Documentation of an active cancer research program, and
- Assurance that the entity is not affiliated or funded by the tobacco industry.

Unsolicited grant applications will not be accepted from, nor will grants be made for, the support of research conducted at for-profit institutions, federal government agencies (including the National Laboratories), or organizations supported entirely by the federal government (with the exception of postdoctoral fellowship applications) or organizations, such as Foundations operated by, and for the benefit of, Veteran Affairs Medical Centers, whose primary beneficiaries are federal government entities. Applications may be submitted by qualified academic institutions on behalf of Veteran Affairs Medical Centers, provided that a Dean's Committee Memorandum of Affiliation is in effect between the two institutions. Principal investigators who are US citizens or Permanent Residents working at a not-for-profit institution in the United States may request under special circumstances, that a component of the research be performed at a foreign institution as a subcontract. In these cases, the principal investigator must convince the Society and its review committees that the proposed research cannot be undertaken at an institution in the United States, and that the findings will be relevant to the US population. See the Research Scholar Grant Instructions under "Detailed Budget: Subcontracts" and "Justification of Budget" for more information.

Although applicants may apply for multiple awards, a grantee may not be the principal investigator on more than one Research Scholar Grant at any time. An exception is made for recipients of grants that are in response to RFAs and for PIs of Institutional Research Grants.

5. RESPONSIBILITY OF THE GRANTEE INSTITUTION

The American Cancer Society does not assume responsibility for the conduct of the activities that the grant supports or the acts of the grant recipient as both are under the direction and control of the grantee institution and subject to the institution's medical and scientific policies. Grantee institutions must safeguard the rights and welfare of individuals who participate as subjects in research activities by reviewing proposed activities through an Institutional Review Board (IRB), as specified by the National Institutes of Health Office for Human Research Protections, US Department of Health and Human Services Furthermore, grantee institutions must adhere to DHHS guidelines regarding financial conflicts of interest, recombinant DNA, research misconduct, and vertebrate animals. These policies apply to applicants and applicant institutions as well.

To signify agreement by the institution, an application for a grant must bear the signature of the official authorized to sign for the institution. Signature of the department head is also required. Additional signatures are at the discretion of the institution.

6. TOBACCO-INDUSTRY FUNDING AND CONFLICTS OF INTEREST

Scientific investigators or health professionals who are funded by the tobacco industry for any project, or whose named mentors in the case of mentored grants are funded by the tobacco industry for any project, may not apply and will not be eligible for American Cancer Society research and training grants activated on or after July 1, 2005. Scientific investigators, health professionals, or named mentors who accept funding from the tobacco industry for any project during the tenure of an American Cancer Society research or training grant must inform the Society of such funding, whereupon the American Cancer Society grant will immediately be terminated. Tobacco industry funding includes: funds from a company that is engaged in, or has affiliates engaged in the manufacture of tobacco produced for human use; funds in the name of a tobacco brand, whether or not the brand name is used solely for tobacco goods; funds from a body set up by the tobacco industry or by one or more companies engaged in the manufacture of tobacco goods.

The following do not constitute tobacco industry funding for the purposes of this policy:

- Legacies from tobacco industry investments (unless the names of a tobacco company or cigarette brand are associated with them);
- Funding from a trust or foundation established with assets related to the tobacco industry but no longer having any connection with the tobacco industry even though it may bear a name that (for historical reasons) is associated with the tobacco industry.

Tobacco industry funding is defined for purposes of Society grants and awards applicants and recipients as money provided or used for all or any of the costs of the research, including personnel, consumables, equipment, buildings, travel, meetings, and conferences, running (operating) costs for laboratories and offices, but not meetings or conferences unrelated to a particular research project.

7. PEER REVIEW OF APPLICATIONS

The Society's Scientific Program Directors distribute the applications to the most appropriate Peer Review Committee and then assign each application to at least two committee members for review. Each committee generally has between 12 and 25 members who are leaders in their areas of expertise, plus up to three "stakeholders." A stakeholder is an individual usually without formal training as a scientist or health professional who has a strong personal interest in advancing the effort to control and prevent cancer through research and training. This interest could stem from an intimate experience with the disease, such as survivorship, a family cancer experience, or being a caregiver.

Depending on the grant applied for, the committees evaluate applications based on some or all of the following criteria: (a) the scientific merit, originality, and feasibility of the application; (b) the qualifications, experience and productivity of the applicant, and the members of the investigative team; (c) the facilities and resources available; and (d) the promise of the research or training as related to the control of cancer or to the benefit to be gained by persons with cancer. At the Peer Review Committee meeting, the applications are discussed and a priority score is voted for each one. Written evaluations of each application are provided to the Council for Extramural Grants (the Council). The Council is a multidisciplinary panel of senior scientists, many having previously served on a Peer Review Committee serving as an ex officio, non-voting member. After considering the relative merit of the applications, the amount of available funds and the Society's objectives, the Council establishes the payline to determine which grants will be funded during each cycle. No voting member of a Peer Review Committee or of the Council may serve concurrently on the Board of Directors or the National Assembly of the American Cancer Society.

Applications that are not funded may be revised and resubmitted twice. Resubmitted applications will be reviewed in the same detail and compete on an equal basis with all other new applications. (See Instructions for additional information on resubmission of applications.)

8. APPLICATION DEADLINES

Applications for grants and awards must be submitted as paper copies in addition to submitting them electronically via proposalCENTRAL. proposalCENTRAL is a consortium of non-profit granting agencies, developed and hosted by Altum. Access is available using links provided in

the American Cancer Society web site <u>www.cancer.org</u> (*see Instructions*). The electronic applications must be submitted and the paper copies received at the Society's National Home Office by close of business (5:00 PM EST) on the specified deadline date. <u>If the deadline falls</u> on a weekend or holiday, applications will be accepted the following business day.

No supplemental materials will be accepted after the deadline unless requested by staff for administrative purposes or when needed for the reviewers. The schedule for application receipt and review is provided in the following table.

Deadline for Peer During to the second secon						
GRANTS	Receipt of Applications	Review Meeting	Preliminary Notification	Council Meeting	Grantee Notification	Activation
Research Scholar	April 1	June	August	Sept.	October	January 1
Grant	October 15	January	March	March	April	July 1
Mentored	April 1	June	August	Sont	October	January 1
Research Scholar	October 15	January	March	Sept. March	April	July 1
Grant	00000115		Iviaicii	waten	1	July I
Postdoctoral	April 1	June	August	Sept.	October	January 1
Fellowship	October 15	January	March	March	April	July 1
Institutional	April 1	June	August	Sont	October	January 1
Research Grant	Артт	Julie	August	Sept.	October	January 1
Physician						
Training Award	April 1	June	August	Sept.	October	January 1
in Cancer	Артт	June	August	Sept.	October	January 1
Prevention						
Research	April 1	June	NA	Sept.	October	January 1
Professor Award	Артт	June	INA	Sept.	October	January I
Doctoral						
Training Grant	October 15	January	March	March	April	July 1
in Oncology	00000115	January	Iviaicii	Iviarcii	Арт	July I
Social Work						
Clinical						
Research	October 15	January	NA	March	April	July 1
Professor Award						
Master's						
Training Grant						
in Clinical	October 15	January	March	March	April	July 1
Oncology Social						
Work						
Cancer Control						
Career	October 15	January	March	March	April	July 1
Development		J			- r	j -
Award						
Doctoral Degree						T 1 1
Scholarship in	October 15	January	March	March	April	July 1
Cancer Nursing						
Graduate						
Scholarship in	February 1	March	N/A	April	May	July 1
Cancer Nursing				1		2
Practice						

DEADLINE, REVIEW, NOTIFICATION, AND ACTIVATION SCHEDULE

9. NOTIFICATION OF APPLICATION RECEIPT AND REVIEW

Approximately one month after receipt of the application, the applicant will receive an email acknowledgment providing an application number, the assigned Peer Review Committee, and the name and telephone number of the Scientific Program Director of the Peer Review Committee. This email will be sent to the address in the Professional Profile supplied at the time of submission.

Preliminary Notification. Following review, preliminary information regarding the status of an application will be emailed along with instructions to download copies of the reviewers' critiques. The letter of notification will also indicate the <u>likelihood</u> of funding as described by one of the following phrases: experience suggests that (a) your application will be funded, (b) we cannot predict at this time or, (c) your application will not be funded. Please note that all final funding decisions are made by the Council for Extramural Grants which typically meets in March and September.

Applicants may call the Extramural Grants Department at anytime during the review cycle. The Program Director will shepherd your application through the entire process. Following receipt and careful consideration of the critiques, applicants are encouraged to contact their Program Director to discuss their review. For those applicants considering resubmission, it is strongly encouraged that they contact their Program Director well in advance of the next deadline.

10. GRANT PAYMENTS

Grant payments will be made at the end of each month, except for nursing scholarships and social work grants, which are made once yearly at the beginning of the year. The American Cancer Society requires that all payments are made to the sponsoring institution and are mailed to the address indicated on the grant activation form. Acknowledgment of payment by the sponsoring institution is not required.

Personnel compensated in whole or in part with funds from the American Cancer Society are not considered employees of the Society. Institutions are responsible for issuing the appropriate IRS tax filings for all individuals receiving compensation from American Cancer Society grants and are responsible for withholding and paying all required federal, state, and local payroll taxes with regard to such compensation. Thus, these and any other tax consequences are the responsibility of the individual recipient and the sponsoring institution. We advise all grant and award recipients to consult a tax advisor regarding the status of their awards.

11. ANNUAL AND FINAL PROGRESS REPORTS

The following policies apply to Research Scholar Grants, Mentored Research Scholar Grants, and Postdoctoral Fellowships. For all other grants, see the appropriate "Required Progress Reports" sections. Annual and final reports represent a critical part of responsible stewardship of the donated dollars. We greatly appreciate your efforts to assist us in this critical responsibility.

A. Both nontechnical and scientific progress reports are to be submitted each year within six weeks after the first and subsequent anniversaries of the start date of the grant, and final reports are due within six weeks after the grant has terminated. To access the necessary forms for annual and final progress reports, please go to <u>https://proposalcentral.altum.com</u>.

- B. The final report should cover the entire grant period. In the event a grant has been extended without additional funds, the final report is not due until the official termination date of the grant. If the grant is terminated early, a final report must still be completed within six weeks of the termination date.
- C. Reports are to be submitted in a timely manner. If this is not possible, <u>a written request</u> to extend the reporting deadline must be made. Otherwise, noncompliance may result in the withholding of payment on all grants in effect at the recipient institution until reports are received.

12. PUBLICATIONS AND OTHER RESEARCH COMMUNICATIONS

Publications resulting from research or training activities supported by the American Cancer Society must contain the following acknowledgment: "Supported by (insert name of grant and number) from the American Cancer Society." The Society's support should also be acknowledged by the grantee and by the institution in all public communication of work resulting from this grant, including scientific abstracts (where permitted), posters at scientific meetings, press releases or other media communications, and Internet-based communications. Although there is no formal approval process for publications by Society grantees, it is helpful if investigators would notify their Program Directors when manuscripts have been accepted for future publication. This will allow ample time to consider and coordinate any additional public notifications.

13. FINANCIAL RECORDS AND REPORTS

A report of expenditures must be submitted within <u>90 days</u> of the expiration date of the grant as indicated in the award letter. Any change in terms such as a no-cost extension will alter the date that the report is due. There are different reporting requirements for the Institutional Research Grant (please see the "Required Financial Reports" section in the IRG policies). Annual financial reports are not required. To access the necessary forms, please go to <u>https://proposalcentral.altum.com</u>.

Signatures of the principal investigator and the institution's financial officer are required. Any unexpended funds must be returned to the Society.

Reports are to be submitted in a timely manner. If this is not possible, <u>a written request</u> to extend the reporting deadline must be made. Otherwise, non-compliance may result in the withholding of payment on all grants in effect at the recipient institution until reports are received.

Institutions must maintain separate accounts for each grant, with substantiating invoices available for audit by representatives of the American Cancer Society. The Society is not responsible for expenditures made prior to the start date of the grant, costs incurred after termination or cancellation of the grant, or for commitments against a grant not paid within 60 days following the expiration date, or any expenditure that exceed the total amount of the award. (See also section 18, "Cancellation.")

14. EXPENDITURES

American Cancer Society *research* grants are not designed to cover the total cost of the research proposed nor the investigator's entire compensation. The grantee's institution is expected to provide the required physical facilities and administrative services normally available in an institution.

For grants that allow indirect costs, the calculation of allowable indirect costs includes all budget items except equipment. See the Instructions for allowable expenditures for Health Professional Training Grants (Nursing Scholarships, Social Work Training Grants, Cancer Control Career Development Awards and Physician Training Awards in Preventive Medicine).

The Society's *research* grants <u>do not</u> provide funds (direct budget) for such items as:

- Secretarial/administrative salaries
- Student tuition and student fees including graduate and undergraduate; however, tuition is an allowable expense for the principal investigator of a Mentored Research Scholar Grant.
- Foreign travel (special consideration given for attendance at scientific meetings held in Canada)
- Books and periodicals except for required texts for coursework in the approved training plan for MRSGs.
- Membership dues
- Office and laboratory furniture
- Office equipment and supplies
- Rental of office or laboratory space
- Recruiting and relocation expenses
- Non-medical services to patients (travel to a clinical site or patient incentives are allowable expenses)
- Per-diem charges for hospital beds
- Construction, renovation, or maintenance of buildings/laboratories

However, Society research and training grant funds <u>can</u> be used for computer purchases that are for research and training purposes, and can be purchased with direct funds from the equipment budget.

15. OWNERSHIP OF EQUIPMENT

Equipment purchased under American Cancer Society research grants or extensions thereof is for the use of the principal investigator and collaborators. Title of such equipment shall be vested in the institution at which the principal investigator is conducting the research. In the event the American Cancer Society authorizes the transfer of a grant to another institution, equipment necessary for continuation of the research project purchased with the grant funds may be transferred to the new institution. Title to such equipment shall be vested in the new institution.

16. INTELLECTUAL PROPERTY RIGHTS

As a not-for-profit organization supported by public contributions, the Society believes it has the responsibility to adopt policies and practices that enhance the likelihood that potentially beneficial discoveries and inventions will be exploited to the benefit of humankind. It is the desire of the Society that such inventions be administered in such a manner that they are brought into public use at the earliest possible time. The Society recognizes that often this may be best accomplished through patenting and/or licensing of such inventions. Accordingly, the Society

has adopted the following patent policy that is binding on all Grantees and Not-for-profit Grantee Institutions (hereinafter "Grantee"). Acceptance of a grant from the Society constitutes acceptance of the terms and conditions of this policy. It is a goal of the Society that the terms and conditions of this policy not conflict with the established patent policy of Grantee.

- A. All notices required pursuant to this policy shall be in writing, and in this policy, the following terms shall have the meaning set forth below.
 - i. "Invention" shall mean any potentially patentable discovery, material, method, process, product, program, software or use.
 - ii. "Funded Invention" shall mean any Invention made in the course of research funded in whole or in part by this Society grant.
 - iii. "Public Disclosure" shall mean any publication, presentation, offer for sale or any activity that would affect the patentability of the invention under 35 USC. § 102 or 103.
 - iv. "Net Income" shall mean gross income received by Grantee in respect of a Funded Invention less inventor distributions in accordance with Grantee policy, payments to joint holders of Funded Invention, and unreimbursed directly assignable out-of-pocket expenses resulting from patenting and licensing for Funded Invention.
- B. Grantee shall notify the Society of each Funded Invention made by Grantee within thirty (30) days after the disclosure of the Funded Invention to Grantee's Technology Transfer Office or the equivalent thereof. Grantee shall promptly determine whether it desires to seek patent or other statutory protection for all Funded Inventions promptly after each Funded Invention is made and shall promptly inform the Society of all decisions to seek or not seek such protection. The Society shall have the right to seek patent or other statutory protection or has failed to file an application for such protection within six (6) months after disclosure of the Funded Invention to the Society, and, upon the Society's request, Grantee shall file for patent protection for Funded Invention in such countries as directed by Society at the Society's expense.
- C. Grantee shall promptly notify the Society of the filing and issuance or grant of any application for a patent or other statutory rights for a Funded Invention and shall keep the Society reasonably informed of the status and progress of all such applications. Grantee shall pay all costs and expenses incident to all applications for patents or other statutory rights and all patents and other statutory rights that issue thereon owned by Grantee (other than as provided for in Sections B or C). Grantee shall also notify the Society at least sixty (60) days in advance of Grantee's intention to abandon any application for a patent or other statutory right for a Funded Invention or not to take action required to maintain any such application or any patent or other statutory right in a Funded Invention, in which event, at the request of the Society, Grantee shall continue patent protection for Funded Invention as directed by Society at the Society's expense (unless maintenance of such patent rights is inconsistent with Grantee's good name).

- D. Each of the Society and Grantee (the appropriate Grantee technology transfer officer managing Funded Invention) shall promptly inform the other of any suspected infringement of any patent covering a Funded Invention and of any misappropriation, misuse, theft or breach of confidence relating to other proprietary rights in a Funded Invention. Grantee and Society will discuss in good faith further action to be taken in this regard.
- E. Grantee shall notify the Society within thirty (30) days of grant of a license, lease, or other revenue generating agreement involving a Funded Invention. In the event that Grantee fails to license a Funded Invention within five (5) years from the issuance of a patent for the Funded Invention and the Grantee has determined no viable means of commercialization for Funded Invention, Grantee shall license the Funded Invention, with the right to sublicense, to the Society (under standard Grantee license terms on a royalty free basis). However, should the Society receive any revenue from sublicensing the Funded Invention, it will share that revenue with Grantee on a mutually acceptable basis.
- F. Grantee will license a Funded Invention in accordance with Grantee Policy and established practices.
- G. i. The Society waives the receipt of income until the Net Income from the Funded Invention exceeds \$500,000.
 - ii. Once the Net Income from a Funded Invention exceeds \$500,000, Grantee shall pay the Society annually a percentage of the Net Income from the Funded Invention that is proportionate to the Society's proportion of the financial support for the research that resulted in the Invention. Such royalty payment shall be accompanied by an appropriate statement of account detailing the amount and showing the calculation of Net Income received by Grantee during the preceding year. The Society shall have the right to audit the Grantee's books and records annually, in order to verify the Net Income derived annually from any Funded Invention.
 - iii. The percentage of Net Income due the Society from a Funded Invention shall be determined by the parties within 90 days of the date the Society is notified by the Grantee (to be extended by mutual agreement of both parties) pursuant to Section E above of the grant of a license, lease or other revenue generating agreement involving the Funded Invention.

If the parties are unable to agree on the percentage of Net Income payable to the Society or any amount owed to Grantee pursuant to Paragraph E above, the dispute (the "Dispute") shall be resolved as follows:

One of the parties shall request (the "Negotiation Request") that each of the parties appoint a designated executive management representative to meet for the purpose of endeavoring to resolve such Dispute. The designated executive representatives, who shall not have been directly involved in the initial negotiations, shall discuss the Dispute and negotiate in good faith in an effort to seek a resolution. During the course of such negotiation, all reasonable requests made by one party to the other for information will be honored so that each of the parties may be fully

advised regarding the Dispute. If the designated executive representatives are unable to resolve the Dispute within 30 days after the Negotiation Request, the parties shall mediate the Dispute with a mutually acceptable mediator within the 30-day period beginning 31 days after the Negotiation Request. If the Dispute is not resolved by mediation within 60 days after the Negotiation Request, either party may initiate arbitration by delivering an arbitration demand to the other party (initiator of arbitration will travel to venue of other party), and the Dispute shall be settled by arbitration in accordance with the Commercial Arbitration Rules of the American Arbitration Association ("AAA"), except that

- (a) there shall be one arbitrator mutually agreed upon by both parties within 30 days after initiation of arbitration and if the parties are unable to agree upon an arbitrator, the arbitrator shall be appointed by AAA;
- (b) neither party may submit more than 20 interrogatories, including subparts;
- (c) neither party shall be entitled to take more than two depositions and no deposition shall last more than two hours;
- (d) all discovery shall be concluded within 90 days of serving the arbitration demand;
- (e) each party shall bear its own costs and expenses and attorney's fees and an equal share of the arbitrator fees and any administrative fees of the arbitrator; and
- (f) arbitration shall not be utilized if Grantee is prohibited by law from submitting itself to binding arbitration.

The award of the arbitrator shall be binding, and judgment upon the award rendered by the arbitrator may be entered in any court having jurisdiction thereof.

17. EXTENSION OF TERM OF GRANT/TRANSFERS

The termination date of any grant may be extended for up to one year without additional funds upon written request to the Program Director from the principal investigator. Please include with the request an estimate of the funds to be carried over into the extension, and an explanation for the delay in completion of the specific aims. The Program Director must receive a written request 30 days before the expiration date of the grant. Requests for a leave of absence will be handled on a case-by-case basis. An extension of term request form can be found at <u>https://proposalcentral.altum.com</u>.

To transfer or change institutions during a grant period, request forms can be found at the same site as above.

18. CANCELLATION OF GRANT

If a grant is to be canceled prior to the original termination date, contact your Program Director and please fill out and submit the Request for Cancellation form which can be found at <u>https://proposalcentral.altum.com</u>.

In the event a grant is canceled, the institution is only entitled to the prorated amount of the award accumulated between the start and termination dates. The Society cannot assume responsibility for expenditures in excess of payments already made to the grantee institution prior to the effective date of cancellation; following cancellation or termination of a grant, no additional payments will be provided to the institution, and all unexpended funds must be returned to the Society

Please note that if the award is to be canceled after initiation of the grant period, a final report will be due within 6 weeks of the termination date describing the work completed up to that point.

For Master's Training Grants in Clinical Oncology Social Work, Doctoral Training Grants in Oncology Social Work, Graduate Scholarships in Cancer Nursing Practice, and Doctoral Degree Scholarships in Cancer Nursing, withdrawal from the graduate program requires cancellation of the grant.

19. DESCRIPTION OF POSTDOCTORAL FELLOWSHIPS

Postdoctoral Fellowships are designed to support a program of research training and study to enable a new investigator to qualify for an independent career in cancer research. The Peer Review Committee reviewing the application will consider whether the fellowship broadens the applicant's research training and experience.

An application for a Postdoctoral Fellowship must be endorsed by the applicant's proposed mentor and the head of the department in which the training will be conducted. A plan of training must be formulated and agreed on by the mentor and the applicant, and described in detail in the application. Preliminary data included in the application must be carefully attributed to the person/s responsible. **Unfunded applications for Postdoctoral Fellowships may only be resubmitted once**.

20. TERM AND ELIGIBILITY RULES

Applicants must have obtained their doctoral degree prior to activation of the fellowship and may apply for one, two, or three-year fellowships. The Society uses the application deadline date to determine the eligibility and duration of fellowship awards. The following table may be used to clarify eligibility:

At the time of application, if PhD or MD has been held:	American Cancer Society eligibility (based on application deadline date)
0 to < 2.0 years	3 years
2.0 to < 3.0 years	2 years
$3.0 ext{ to} < 4.0 ext{ years}$	1 year

Individuals who have held a PhD or MD for more than 4 years at the time of application generally are not eligible for a Fellowship. However, the following are not considered in the determination of eligibility:

- **Exempt Training**—Internships, residencies, and oncology subspecialty training (clinical fellowships) are not considered as research training, and do not count toward the four year limit beyond the terminal degree.
- Leave of Absence— An appropriately documented leave of absence will not be counted in the years of eligibility. Leaves of absence may include: military service, family leave, and teaching in a non-research position.

Revised applications may be submitted if the applicant meets the eligibility requirements. Revised applications will be reviewed in the same detail and compete on an equal basis with new applications (see Postdoctoral Fellowship Instructions).

21. FUNDS

A Postdoctoral Fellowship consists of a stipend and fellowship allowance. For details see the Instructions, Section 5.

Stipend: Awards are made for one to three years with progressive stipends of \$44,000, \$46,000, and \$48,000 per year. The annual stipend may be used solely for the salary support of the fellow. The institution may supplement the Society's contributions from other sources. However, an awardee may not hold a Postdoctoral Fellowship Award from another funding source (Federal or Non-Federal) at the same time as the American Cancer Society Award. The American Cancer Society does not withhold any amount for income tax purposes. The applicant should contact the Internal Revenue Service to determine the tax status of the fellowship.

Fellowship Allowance: \$4,000 per year may be requested to help defray costs incurred at the fellow's training institution for the benefit of the fellow. Examples of such costs are: health insurance, travel to scientific meetings, etc. Institutional indirect costs may **not** be recovered from these funds.

22. CHANGE OF INSTITUTION/MENTOR

It is incumbent upon the grantee to discuss any change in institution and/or mentor with the Program Director.

Change of institution: Recipients of a Postdoctoral Fellowship may transfer their grant from one institution to another only after receiving written approval from the Society. Prior to transfer, the American Cancer Society must receive the following:

• A request for transfer in writing, indicating the anticipated transfer date. If the mentor and/or project will also change, please refer to section below "Change of Mentor."

• A statement from an administrative official at the original institution relinquishing the grant.

• The final Report of Expenditures from the original institution together with a check for any unexpended funds; to access financial reporting forms, please go to https://proposalcentral.altum.com.

• Postdoctoral Fellowship transfer forms (title page, contact information page, and assurances and certification page of the Postdoctoral Fellowship application form) completed by

the appropriate individuals at the new institution-indicating acceptance of the grant. To access the transfer forms, please go to <u>https://proposalcentral.altum.com</u>.

• Payments to the new institution will not be initiated until a final accounting and a check for any unexpended funds have been received from the original institution and the transfer has been approved by the Society. This final financial report must be submitted within 60 days of the date the transfer was requested.

Change of mentor: A change of mentor for the recipients of Postdoctoral Fellowships is not routinely allowed but will be considered on a case-by-case basis. Contact the appropriate Scientific Program Director for further information. If a change in mentor also involves a change in project and/or institution, a new application may be requested.

APPENDIX: INSTRUCTIONS FOR SUBMITTING DELIVERABLES:

GRANT ACTIVATION FORMS ANNUAL PROGRESS/FINAL REPORTS TRANSFER REQUEST CHANGE OF INSTITUTION CHANGE OF TERM EXTENSION OF TERM GRANT CANCELLATION CHANGE OF PRINCIPAL INVESTIGATOVR REPORTS OF EXPENDITURES

The American Cancer Society is pleased to announce our continued association with Altum proposalCENTRAL by subscribing to the **Post Award Management System**. The system is designed to collect grant post award information from grantees. Grantees are asked to keep their proposalCENTRAL profile current for the duration of the grant.

The site is used to upload all requests for grant changes and related documents, and required reports (deliverables). The site will house all reports, requests and correspondence pertaining to a grant and is accessible to both ACS program staff and grantees. Grantees may provide access to others at their institution (e.g. grants officers) using the instructions provided below.

All awardees of an ACS grant will need to upload deliverables, and then send an email (correspondence) to the Program Director/Program Coordinator informing the program office of the submitted deliverables. The first deliverable we will be collecting through the **Post Award Management System** is the "Activation Form." For the Activation Form <u>only</u>, please also email Melissa Kelly at <u>melissa.kelly@cancer.org</u> in the Research Business office notifying her that you have uploaded your Grant Activation Form.

Uploading an Award Deliverable

- Log onto https://proposalcentral.altum.com
- PI must enter their ProposalCentral username and password in "Applicant Login" to access their award detail information
- Click on the Awarded link or all Proposal link
- In the Status column, click on the Award Details link
- On the Award Details screen, click on the Deliverables link at the bottom of the screen

The schedule of deliverables due for the award is shown chronologically.

- Go to the **Deliverables Templates** section at the bottom section of the screen to select the appropriate template
- Download and save the template to your computer and complete it.
- To Submit Grant Deliverables and other documents, click the Upload link next to the scheduled deliverable and date
- Click "Browse" button to select the file from your computer.

- Click Save to upload the deliverable. You can replace the uploaded document with another document by clicking Browse....again, selecting a different document from your computer files and click the Save (Adding description of deliverable is optional)
- Click Close

Send Email (Correspondence) to an ACS Administrator

- To send correspondence to Program Director at the ACS, click the "Correspondence" link from the Award Details screen
- From this page, you can see any correspondence that has already been sent by clicking on the Blue link in the Message column
- Use the Respond link to respond directly to a message you have received
- To send a new message, click "Send Correspondence to Program Director" at the top of the page
- Select the administrator(s) who should receive the correspondence email
- Enter a subject and text for the correspondence in the spaces provided
- Click the "Send Email" button to send the email(s) to the selected administrator

Once an application is awarded it moves from proposalCENTRAL into the Post Award Management System. People who previously had access to your application in proposalCENTRAL will not have access to your awarded grant in the Post Award Management System. You may need to allow access to different users than those listed in proposalCENTRAL to enable them to upload various reports on your behalf.

To allow to another user access to your award and to submit deliverable

- Person(s) must be a registered user on proposalCENTRAL. If they are not, ask them to register as a new user at:

https://proposalcentral.altum.com/login.asp

- Once user is registered, from Award Detail screen click Contacts and User Access link
- Click on Manage User Access To Award at the top of the screen
- Enter and confirm email address of person
- Click on Add button
- Change the Permissions role from View to Administrator
- Click on Save button to activate access for new person

To upload other documents such as Publications, CV, etc...:

- Click the "Add Deliverable" link on the Award Deliverable screen
- Select "Other" from the drop down menu next to "Deliverable Type" from the pop up screen
- Type in the "Deliverable Description" (i.e. Publications; CV; etc...)
- Click "Browse" to upload their document
- Click "Save"

Additional information and help can be obtained through proposalCENTRAL customer support desk:

By phone: 1-800-875-2562 toll free By email: <u>pcsupport@altum.com</u>

POSTDOCTORAL FELLOWSHIP

INSTRUCTIONS

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A. GENERAL INFORMATION

1. APPLICATION SUBMISSION AND REQUIRED SIGNATURES

Applications must be submitted in two formats: an electronic version and paper copies (original printed electronic application with official signatures plus three copies). The electronic version is submitted using links provided in the American Cancer Society web site <u>www.cancer.org.</u>

The original copy of the application must carry the signatures (front page) and contact information (second page) for

- The Applicant
- The Institutional Signing Official
- The Department Head

See program specific instructions for additional required signatures.

The electronic applications must be submitted and the paper copies of the application must be received by the Society's National Home Office by close of business (5:00 PM Eastern time) on the specified deadline date. If the deadline date falls on a weekend or holiday, applications will be accepted the following business day.

Contact Altum at 1-800-875-2562 or email, <u>pcsupport@altum.com</u> to address any problems with preparation or submission of the electronic version of the application.

2. FORMATTING THE APPLICATION

Applicants must adhere to the following instructions in completing the proposal sections that make up the electronic version of the application. <u>Failure to observe type size specifications</u> and/or page limits will result in the return of the application without review:

- Please remember to insert your name in the header for each section of the application
- All application documents should be single-sided.
- **Type size**: Use 12 point Times New Roman or 11-point Arial as the minimum font size for the text of the application. A 10-point Times New Roman or 9-point Arial font type may be used for figures, legends, and tables.
- Single-spaced text is acceptable, and space between paragraphs is recommended.
- **Margins**: The margins of your text should be at least one inch all around, unless a form with different margins is supplied in the Application Templates.
- Page numbering:

Cover Pages. The first few pages of the application form are considered cover pages and are not numbered. The cover pages include the Signature Page, Contact Page, and General Audience Summary.

Proposal Sections. The proposal sections are listed in the Table of Contents and must be numbered in the upper right hand corner. Each section should be numbered independently.

• **Appendix**: Material in the application appendix which is not a part of the electronic application will not be furnished to the entire Peer Review Committee; therefore, it is

advisable to include tables, figures, or photographs that are essential for the evaluation of your research plan in the main body of the application.

3. RESUBMISSION OF AN APPLICATION

Applications that are not funded may be resubmitted twice (except Postdoctoral Fellowships which may only be resubmitted **once**). Applicants are strongly encouraged to contact the appropriate Program Director prior to resubmission to discuss the previous reviews. Please follow these guidelines when resubmitting an application:

- Submit a complete application with a current date—electronic and paper copies.
- When resubmitted, the title of the project can be altered if necessary but should be appropriately marked as a first or second resubmission.
- Select the appropriate application number from the list of your prior submissions on proposalCENTRAL.
- The review committee code (e.g. TBE, CCE, CPPB, etc.) for the previous application must be provided where requested on the title page.
- A "Reply to Previous Review", not to exceed 3 pages, should be placed where indicated in the Table of Contents of the Application Templates section. It should clearly and briefly address the points raised in the previous review and direct the reader to the specific sections of the text where revisions have been made. Revised portions of the text changed in response to the reviewers' comments should be highlighted (e.g.: bold type, line in the margin, underlining, etc.). Copies of the reviewers' previous critiques should be inserted immediately after the Reply to Previous Reviews as illustrated in the Table of Contents.
- For resubmission only, a photocopy of the notarized citizenship document is acceptable.

4. CHANGES TO THE APPLICATION

Withdrawal of application: Please advise the Society promptly, in writing, should you decide to withdraw your application for any reason. Your letter (or email) to the Program Director identified in the application acknowledgment letter should include your name, the application number, and the reason for withdrawal.

Change of address: Notify the Society in writing (email) of any changes of address, email or phone number, following the submission of an application. Include your name and the application number. **Change of institution:** If you are an applicant for an ACS grant and change your institution, contact the Program Director identified in the acknowledgment email, who will determine whether your application can be reviewed.

5. ACCESSING THE ACS GRANT APPLICATION SYSTEM

NOTE: In order to use the electronic grant application system, including printing copies and electronic submission, it is recommended that you have Adobe Acrobat Reader 5.0 or above. In addition, the system requires a compatible browser. Recommended for Windows is Internet Explorer 6,7 and 8, Firefox 3.0 and 3.5, Safari 3.1 and 4.0 (for Mac Users, although they can also download and use Firefox). In addition to the full version of Adobe Acrobat which can convert documents to PDF, Microsoft has an add-on for Office 2007 called the "XPS and PDF document

converter" (or something similar) which is a free download for people who have licensed copies of Office 2007. It can convert any Word or Excel file into a read-only PDF.

Access the American Cancer Society Research site at www.cancer.org.

- Select "Explore Research" followed by "Research Programs and Funding" > "Funding Opportunities" > Index of Grants.
- Select the grant for which you are applying. You are now able to access the electronic grant application process at proposalCENTRAL.
- Once you reach proposalCENTRAL, follow their instructions to login/register and to complete and submit an application.
- The key steps for starting an application are as follows:
 - Click on "Create New Proposal" to select a grant program and start your grant application. Locate the appropriate grant and click on "Apply Now" to create a proposal. Enter a Project Title (unless one is provided) and click SAVE. Once you have clicked on the "Save" button, the links to the other pages of the application appear in the Proposal Sections menu. Your saved application is stored under the "Manage Proposals" tab.

Please note: Detailed information is available through tutorials, provided on the proposalCENTRAL login page.

If you have problems accessing or using the electronic application process, click on "Help" or contact ALTUM Customer Service at <u>pcsupport@altum.com</u> or 1-800-875-2562.

6. EXPLANATION OF REQUIRED INFORMATION

Please note: Not all fields are required for all applications.

Project Title: The title should not exceed 75 characters in length (including spaces). Do not use abbreviations unless absolutely necessary.

Principal Investigator/Applicant Information: Some (or all) of the required information will have been automatically filled in from your profile. The information was provided when you initially registered with proposalCENTRAL and completed the Professional Profile. If any of this information is not current at the time of submission, you will need to update the Professional Profile before finalizing this section and submitting the final version of your application.

Key Personnel. In addition to the Principal Investigator, Key Personnel are defined as individuals who contribute to the scientific development or execution of the project in a substantive, measurable way whether or not salaries are requested. Typically, these individuals have doctoral or professional degrees although individuals at the masters or baccalaureate level can be included if their contribution meets the above definition of Key Personnel.

Citizenship Status: An appropriate selection must be made in the Professional Profile. At the time of the application, applicants must be US citizens, noncitizen nationals, or permanent residents of the US. Permanent residents must submit with the application notarized evidence indicating that they have a Resident Alien Card or "Green Card" (I-551) or have been approved for the issuance of such card as evidenced by an official passport stamp of the United States

Immigration Service or I-797 Notice of Action indicating approval has been obtained. Noncitizen nationals are persons who, although not US citizens, owe permanent allegiance to the United States. They are generally persons born in outlying US possessions (e.g., American Samoa and Swains Island).

Justification of Eligibility: Applicants for American Cancer Society Extramural Grants must satisfy the eligibility requirements. If required, indicate the month and year your last degree was conferred, as well as the month and year of your first independent faculty (or equivalent) position. If your case was evaluated by the American Cancer Society eligibility committee, include the letter as part of the appendix and refer to it in the justification space provided.

Justification of Designation "Priority Program in Health Disparity Research": Indicate on the title page of the application, "Disparities Research" if the proposed study falls into the Priority Focus (Health Disparities Research) in the Cancer Control and Prevention Research Program.

Space: If appropriate, indicate the approximate area of committed, independent research space provided to support your research program, as well as the name of the department chair responsible for verification of this research space. You must insert a value on the electronic form, even if you need to enter a 0 (zero).

Institution Official: In addition to the name and address of the official authorized to sign for the institution, include an address for mailing checks. Institutional official should sign the front page; "Per" signatures are not acceptable.

Department Chair: Indicate name, department, and email address of the department chair. Department chairs should sign the front page to confirm the title of investigator and the committed resources. Department Chairs are strongly advised (but not required) to provide a letter of support for Research Scholar Grant and Mentored Research Scholar Grant applications to convey the level of enthusiasm for the investigator and their program, and to detail the institutional commitments which have been made (e.g. space, start-up support). Such Department Chair support letters can be included in the appendix.

Primary Mentor: Fill out all of the required fields for your mentor information.

Additional Mentor (s): Fill in this section with the same required information as for your primary mentor (when appropriate).

7. GENERAL AUDIENCE SUMMARY

The general audience summary is intended to provide a clear overview of your research and/or training program to people who are *not* trained in the sciences but who are interested in cancer research for a variety of reasons. These include stakeholders, ACS staff members, potential donors and the general public. **Stakeholders** are individuals who usually do not have formal science or oncology training but have a strong personal interest in controlling and preventing cancer and who are voting members of every peer review committee. As part of their review, they are asked to assess the ability of the applicants to describe their research or training to a

non-scientific audience, and this summary contributes to the basis for this evaluation. **ACS staff members** with responsibility for communicating ACS research to the local media use the summaries to describe the research or training funded in the region. **ACS staff members** who work with major donors use the summaries to identify projects appropriate to the interests of donors who wish to support specific areas of cancer research, and then provide them to such **potential donors** to allow them to select projects that are of interest to them, and which they may wish to fund by a specific donation. Last, if an award is made, the summary is made available to the **general public**.

The general audience summary must *not* duplicate the structured technical abstract. It should be written in a way that makes the project easily understood by the audience described above. See **the Samples of General Audience Summaries in the Appendix for examples of a properly constructed summary.** This summary should describe the background to the research or training, the questions to be asked, and the skills or information to be obtained. It should be written in *nontechnical* language, and not contain any scientific jargon. The use of symbols and Greek characters should be avoided for the general audience; if they must be used, they have to be spelled out since they will not appear as characters in the text. The contribution the project is expected to make to the field of study and to cancer in general, or specifically to one or more of the categories identified in Priority Areas in the Appendix, should be made clear. Proprietary and/or confidential information should not be included.

This form is limited to 3,000 characters, including spaces and will truncate at that point. Characters in excess of the limit are not transmitted with the application resulting in an incomplete summary.

8. PROJECT CODING

Please note: not all applications require project coding. Red asterisks indicate required fields. Submit this section electronically only.

Donors frequently have an interest in funding particular types of cancer research. Thus, Research Areas, Priority Areas, and Organ Sites must be selected for these summaries to be presented to donors for special funding opportunities. *See the Priority Areas in the Appendix for filling out the forms.* Please note that in completing the Priority Areas section, appropriate items may also include those listed under Resources and Infrastructure Related to [specific area]. See the Appendix for specific terms and examples.

The information requested is for statistical purposes only and is not part of the application used by the Peer Review Committee for scientific review. Do not submit this section with your paper copy.

9. STRUCTURED TECHNICAL ABSTRACT

Please note: not all applications require a structured technical abstract.

The structured technical abstract is a summary of the proposed research or scholarly project for general scientific audiences. This structured technical abstract should provide a clear, concise

overview of the proposed work, including the background, objective, or hypothesis and its supporting rationale; specific aims of the study; study design; and relevance of the proposed work to the American Cancer Society's mission of eliminating cancer as a major health problem.

Download the Technical Abstract Template and save it to your hard drive. You must use this form for this portion of the application. The abstract will need to be uploaded as an attachment to your application. The abstract attachment must be converted into a .pdf document before it is uploaded. Please see proposalCENTRAL's FAQ or call support at 1-800-875-2562 if you need assistance.

Please use the outline below. See the Appendix for an example of a structured technical abstract.

- **Background**: Provide a brief statement of the ideas and reasoning behind the proposed work.
- **Objective/hypothesis**: State the objective/hypothesis to be tested. Cite evidence or provide a rationale that supports it.
- Specific aims: Concisely state the specific aims of the study.
- **Study design**: Briefly describe the study design, emphasizing those elements you consider most relevant to assignment of the proposal for peer review.
- **Cancer relevance**: Provide a brief statement explaining the potential relevance to cancer of the proposed work.

If this application is funded, this description will become public information. Therefore, do not include proprietary/confidential information.

10. ASSURANCES AND CERTIFICATION

All activities involving human subjects or vertebrate animals must be approved by an appropriate institutional committee before the application will be funded by the American Cancer Society. Furthermore, compliance with current US Department of Health and Human Services guidelines for financial conflict of interest, recombinant DNA, research misconduct, and vertebrate animals is required. The assurances/certifications are made and verified by the signature of the institutional official signing the application.

Vertebrate animals. Every proposed research project involving vertebrate animals must be approved, by an appropriate Institutional Animal Care and Use Committee (IACUC), in accordance with Public Health Service Policy on Humane Care and Use of Laboratory Animals, before the application will be funded by the American Cancer Society. IACUC approvals are valid for a maximum of three years. Enter the date of the most recent IACUC approval in the space provided.

All research supported by the American Cancer Society (including subcontracted activities) involving vertebrate animals must be conducted at performance sites which are covered under an approved Animal Welfare Assurance. Likewise, human subjects must be covered by an approved Assurance of Compliance.

Human subjects. All proposed research projects involving human subjects must be approved by the appropriate Institutional Review Board (IRB). The review date should be recent; certification is invalid if the review date precedes the submission date by more than one year.

The institution must have received approval from the Office for Human Research Protections (OHRP) of the US Department of Health and Human Services (DHHS). Enter the institution's Assurance of Compliance number(s) in the space provided. Copies of the DHHS policy and information regarding the assured status and assurance numbers of institutions may be obtained from OHRP. The definitions and further sources of clarification for all of these assurances are found in the NIH Grants Policy Statement (Revised 12/03), www.grants.nih.gov/grants/policy, or the NIH Office of Extramural Research.

If institutional review of human subjects (IRB certification) or vertebrate animal use (IACUC certification) has not been completed before the submission date of the application, you must indicate that the approval is pending on the certification page and give the appropriate institutional reference numbers if available. Certification of the institutional committee review, clearly labeled with the assigned American Cancer Society application number, must be received prior to activation of a grant application for funding. Failure to supply the American Cancer Society with completed IRB and/or IACUC certifications prior to the approved start of funding will result in withholding of payments and may result in cancellation of funding.

Please note: applications for the Institutional Research Grant and certain Health Professional Training Grants do not require submission of IRB and IACUC certifications. Institutions must, however, be in compliance with the requirements noted above in order to use American Cancer Society grant funding for activities involving human subjects or vertebrate animals.

11. PI DATA SHEET AND RESEARCH PROMOTION INFORMATION

Submit this section electronically only.

The requested information is for statistical purposes only and is not part of the application used by the Peer Review Committee for scientific review. This section will not print with the cover pages and does not need to be submitted with your paper copy.

12. COMPLETING ALL APPLICATION SECTIONS AND PRINTING PAPER COPY

- All application attachments must be uploaded as .pdf documents. See proposalCENTRAL FAQ or contact support at 1-800-875-2562 if you need assistance.
- <u>Validate</u> the application on proposalCENTRAL. This is an essential step. An application that has not been validated cannot be submitted.
- Print application via proposalCENTRAL. To do so, choose "Print" on the menu and select "Print Signature Pages and Attached PDF Files". **Do not print cover pages for an application that has not been validated.**

- If you wish, print and retain for your files the paper copies of the Demographic and Research Promotion Information and the Project Coding sections. Do <u>not</u> submit these sections in the paper copy of your application.
- Prepare the application for your institution's internal authorization process. Obtain the appropriate institutional signatures on the first page.

13. ASSEMBLY AND SUBMISSION OF PAPER COPIES

<u>The paper copies (original application with official signatures plus three copies) must reach</u> the American Cancer Society Extramural Grants Office by 5:00 PM Eastern time on the <u>deadline date.</u>

The paper copies must be assembled as described below. To reduce the chance of losing an application, we urge institutions to mail only one application and its copies per package. If more than one application is included in a package, provide a bright-colored cover sheet listing the applications enclosed and stating in ½ inch or larger lettering "MULTIPLE APPLICATIONS ENCLOSED." All **four sets** of the application (original application with official signatures plus three copies) must arrive in the same package arranged in the following order:

- Original application with official signatures plus an appendix. This is the document that prints when "Print Signature Pages and Attached PDF Files" is selected. This includes Cover Pages, General Audience Summary, Structured Technical Abstract (if applicable), and the Application Templates.
- Three copies of the original application, each copy with an attached appendix.

The original and three copies of the application and appendixes should be held together with a rubber band. Please **<u>do not</u>** staple or bind. Send the complete application package to:

The American Cancer Society Extramural Grants Department 250 Williams Street NW, 6th Floor Atlanta, GA 30303-1002

Note that any accompanying letters that are <u>not</u> included in the appendix are not distributed to the Peer Review Committees.

14. SUBMISSION OF THE ELECTRONIC VERSION

- Get all signatures on the paper copy before submitting. Please note, the original signed copy of the front page is NOT uploaded in the electronic version; it is to be submitted with the paper copies.
- If any modifications were made during the signature process, make certain that all sections of the electronic version are revised to match the paper copy that is being submitted.
- If you have technical questions regarding the electronic application process, feel free to contact Altum at pcsupport@altum.com or 1-800-875-2562.

• Submitting electronic version of application should be done after your institution has prepared the application for mailing. You have until 5:00 PM Eastern time on the deadline date to complete the electronic submission. Note that the appendix materials are not submitted electronically.

Please note: You will <u>not</u> be able to make any changes to the forms or upload any modifications to the files after submission.

B. PREPARING THE APPLICATION

1. COVER PAGE

Program Eligibility Information: Most of the information that is collected online at Proposal Central appears on the cover page. This includes program eligibility information including last degree conferred or pending. This information *is required* to determine eligibility for a Postdoctoral Fellowship. If you have received a letter from the American Cancer Society Eligibility Committee, *manually* indicate this on the cover page in the Program Eligibility Information section and attach the letter in the Appendices.

Additional Signatures Both Department Head and Mentor are required to sign in section "Additional Signatures."

2. APPLICATION TEMPLATES

An application consists of several sections that must be uploaded before the on application is submitted. Templates for these sections are available once an application is started on proposalCENTRAL. The templates must be downloaded to a computer and completed offline using word processing software. Detailed below are the instructions for completing the individual sections. *The sections must be converted into .pdf documents before being uploaded. Please see proposalCENTRAL's FAQ or call support at 1-800-875-2562 if you need assistance.*

3. TABLE OF CONTENTS (PAGE 1.1)

Complete the Table of Contents by indicating the appropriate page numbers for each section; do not exceed one page.

4. STRUCTURED TECHNICAL ABSTRACT (PAGE 2.1)

The structured technical abstract is a summary of the proposed research or scholarly project for general scientific audiences. This structured technical abstract should provide a clear, concise overview of the proposed work, including the background, objective, or hypothesis and its supporting rationale; specific aims of the study; study design; and relevance of the proposed work to the American Cancer Society's mission of eliminating cancer as a major health problem.

Please use the outline below. See the Appendix for an example of a structured technical abstract.

- **Background**: Provide a brief statement of the ideas and reasoning behind the proposed work.
- **Objective/hypothesis**: State the objective/hypothesis to be tested. Cite evidence or provide a rationale that supports it.
- Specific aims: Concisely state the specific aims of the study.
- **Study design**: Briefly describe the study design, emphasizing those elements you consider most relevant to assignment of the proposal for peer review.
- **Cancer relevance**: Provide a brief statement explaining the potential relevance to cancer of the proposed work.

If this application is funded, this description will become public information. Therefore, do not include proprietary/confidential information.

5. BUDGET (PAGE 3.1)

Stipend: The stipend for the Postdoctoral Fellowship is \$ 44,000, \$46,000, and \$48,000 for the first, second, and third years respectively. Fellows eligible for only two years may request \$46,000 and \$48,000 respectively. Fellows eligible for only one year may request \$48,000.

Fellowship Allowance: \$4,000 per year may be requested to help defray costs incurred at the fellow's training institution for the benefit of the fellow. Examples of such costs are: health insurance, travel to scientific meetings, etc. Institutional indirect costs may **not** be recovered from these funds.

6. PENDING FELLOWSHIP APPLICATIONS

List all sources of **current** and **pending** fellowship support with other agencies. Indicate the granting agency, start date, and full term of the award. It is important to keep the Scientific Program Director of the American Cancer Society current on the status of all pending applications.

7. BIOGRAPHICAL SKETCH OF APPLICANT (PAGE 4.1)

Using the **Biographical Sketch** template, complete the biographical information requested. Do not exceed two pages for total biographical information.

Education and Training: Include all degrees awarded: list the year conferred, institution, and field of study, and if awarded a Ph.D., the name of the mentor. Also list postdoctoral training, residency programs, internships. List title of position, mentor's name, institution and exact dates of training.

Positions and Honors: List in chronological order, previous positions, concluding with your present position. State duration, title, and institution. List any honors.

<u>Publications:</u> Give complete references, including titles for all peer reviewed publications; begin each citation on a new line. If the number of publications is extensive, you may give a partial listing; indicate total number of publications (excluding abstracts, non-peer reviewed articles or book chapters). Do not exceed two pages for total biographical information

8. REPLY TO PREVIOUS REVIEW (resubmissions only) (PAGE 5.1)

IF APPLICATION IS A NEW SUBMISSION upload the provided template with "Not Applicable" in the body. For resubmissions this section should clearly and briefly address the points raised in the previous reviews and direct the reader to the specific sections where text revisions have been made. Text changed in response to reviewers' comments should be identifiable in the revised application (e.g. bold type, line in the margin underlining, etc). **Unfunded applications for Postdoctoral Fellowships may only be resubmitted once**.

9. PREVIOUS CRITIQUES (resubmissions only)

Electronic copies of the critiques for you previous submission can be downloaded from your "Submitted" page on proposalCENTRAL. Select the link to "View Review Info" then "View Summary Statement" and save the document to your computer. Upload the document to your new application with the other proposal sections.

10. PLANS FOR WORK UNDER FELLOWSHIP (PAGE 6.1)

The total length of Sections A and B must not exceed 12 pages. Be advised that cogent descriptions are advantageous over verbose text that approaches the page limits. This page limit includes figures but does not include references. Reprints may be submitted in the Application Appendix to document your work. Proposals should be realistic in terms of work to be accomplished during the period of training for which the support is requested. The 12-page limit will be strictly enforced. Applications that exceed this limit or do not conform to the type size limitations (see Section A) will be returned without review.

A. Research Experience: In 3 pages or less, describe any previous investigations; state the nature, results, and where, when, and with whom the work was conducted. Describe how this fellowship will broaden the training and experience beyond what was obtained in graduate work.

B. Research Plan: The total length of this section should not exceed 9 pages. This page limit does not include the references, which should come at the end of the research plan. Proposals should be realistic in terms of work to be accomplished in the period of time for which support is requested. Failure to conform to the guidelines on type size, page length, or project scope will result in the application being returned to the investigator without review. For resubmission of a previous application, see Sec A-3, of these INSTRUCTIONS.

I. **Specific Aims:** List the objectives and goal of the research proposed and describe the specific aims briefly in order of priority

- **II. Background and Significance:** concisely summarize and critically evaluate related work done by others and specifically state how the successful completion of the work proposed in the specific aims of the application will advance scientific knowledge or aspects of clinical practice.
- **III. Preliminary Studies (if available; not required):** Provide results of research accomplished by you and/or others that are relevant to this proposal in a sufficiently comprehensive manner to indicate their significance. Carefully attribute the source of any preliminary data included.
- **IV. Research Design and Methods.** Describe your proposed methods and procedures in sufficient detail to permit evaluation by other scientists. Discuss potential difficulties and limitations of the methods and procedures, and provide alternative approaches.

References should be listed numerically, in order of their appearance in the text. Each reference listed must include the title, names of all authors, book or journal, volume number, page numbers, and year of publication. The page limit does not include references.

C. Statement of Cancer Relevance: This section of the application is important to the Stakeholders (non-scientific members) on the Peer Review Committees and to a number of general audiences including donors. The use of technical terminology or scientific jargon should therefore be avoided. Describe the short term and long term contributions the project is designed to make to the control of cancer. For basic studies not directly involving human cancer cells, explain how the results to be obtained will lead to a better understanding of the disease, or improve our ability to prevent, detect, or treat cancer or cancer patients. For more clinically relevant projects involving the etiology, diagnosis, treatment and/or psychosocial or behavioral aspects of cancer in humans, outline the expected contribution of the study to controlling the overall cancer burden. This description might include: an estimate of the potential patient target population; anticipated effects on morbidity and/or mortality; possible impact on quality of life; and the extent to which the findings may be applicable beyond the specific aspect of cancer to be investigated. This section should not exceed 250 words.

D. Career Goals: Indicate the type of position you wish to obtain following completion of the fellowship and what you wish to accomplish.

11. LETTERS OF RECOMMENDATION (PAGE 7.1)

List the name, title and address of three individuals *other than the proposed mentor*, who can and will critically appraise your qualifications. Optimally, the letters should be from the graduate mentor, members of the former dissertation committee, and former research mentors. The letters should include comments on character, motivation, maturity, general knowledge, ability to use research techniques, originality, and specialized experience, and training. The letters will need to be provided electronically on proposalCENTRAL. Provide the email addresses and names of the persons you ask to provide letters of recommendation in the Letter of Recommendations section of the online application. This allows proposalCENTRAL to email those individuals a link to the website and give them access to the site to upload their letters. There are specific instructions on the site for you and your recommenders. Your application should not be submitted until these letters have been provided on proposalCENTRAL.

12. TRANSCRIPTS

A transcript of graduate and/or medical school records must be included as part of the application in the <u>appendix</u> (an original plus three copies). If the terminal degree has been awarded, the date of its receipt should be indicated on the transcript. While an original is preferable, a photocopy or Adobe document version is acceptable.

PART II

The following sections must be prepared by the proposed mentor. If there are co-mentors, only the primary mentor should complete PART II (except for the Biographical Information requested in #16; both mentors should submit this information).

13. PROPOSED TRAINING (PAGE 8.1)

Describe the program proposed for the applicant covering the full period of training requested. All phases of training, research and didactic, must be included. *This information will be used to evaluate the quality of the training experience and is an integral part of the overall assessment of the application. Therefore, the mentor is encouraged to include any information which will aid this evaluation.* For example, state the number of Postdoctoral Fellows and Graduate Students in the laboratory, and, if applicable, indicate approximately how many graduate students and fellows have completed their training in the mentor's laboratory during the past 3-5 years. Comment on the importance of the proposed research to cancer. State whether the proposed research plan in Section 5 was prepared independently by the applicant or in collaboration with you. Any comments about the postdoctoral applicant should be included here rather than including a separate letter.

14. FACILITIES AVAILABLE (PAGE 9.1)

Describe briefly the facilities available for the training program proposed.

15. BIOGRAPHICAL SKETCH OF MENTOR(S) (PAGE 10.1)

Include your name (last, first, degree), present title, and pertinent publications; do not exceed two pages. If a partial listing of publications is given, indicate the total number (excluding abstracts, non-peer reviewed articles, and book chapters). All mentors should submit biographical information.

16. SUPPORT OF MENTOR (PAGE 11.1)

List all active and pending grant support including granting agency, title of project, total amount, and term.

17. APPLICATION APPENDIX

All supplementary materials (reprints, preprints, transcripts, etc.) included in the appendix should be listed in the Table of Contents. If the applicant is not a US citizen, a notarized copy of proof of Permanent Resident status should be included in the appendix. Note that the appendix is not duplicated for the entire committee and applicants are urged to keep this section as brief as possible. Include an appendix for each paper copy submitted.

APPENDIX A: CLASSIFICATION CATEGORIES

Biology

1.1 Normal Functioning

Examples of science that would fit:

- Developmental biology (from conception to adulthood) and the biology of aging
- Normal functioning of genes, including their identification and expression, and the normal function of gene products, such as hormones and growth factors
- Normal formation of the extracellular matrix
- Normal cell to cell interactions
- Normal functioning of apoptotic pathways

1.2 Cancer Initiation: Alterations in Chromosomes

Examples of science that would fit:

- Abnormal chromosome number
- Aberration in chromosomes and genes (e.g., in chronic myelogenous leukemia)
- Damage to chromosomes and mutation in genes
- Failures in DNA repair
- Aberrant gene expression
- Epigenetics
- Genes and proteins involved in aberrant cell cycles

1.3 Cancer Initiation: Oncogenes and Tumor Suppressor Genes

Examples of science that would fit:

- Genes and signals involved in growth stimulation or repression, including oncogenes (Ras, etc.), and tumor suppressor genes (p53, etc.)
- Effects of hormones and growth factors and their receptors such as estrogens, androgens, TGF-beta, GM-CSF, etc.

1.4 Cancer Progression and Metastasis

- Latency, promotion, and regression
- Expansion of malignant cells
- Interaction of malignant cells with the immune system or extracellular matrix
- Cell mobility including detachment, motility and migration in the circulation
- Invasion
- Malignant cells in the circulation including penetration of the vascular system and extrasavation
- Systemic and cellular effects of malignancy
- Tumor angiogenesis and growth of metastases
- Role of hormone or growth factor dependence/independence in cancer progression

1.5 Resources and Infrastructure (*Note:* grants coded as 1.2 in previous versions of the CSO become 1.5)

Examples of science that would fit:

- Informatics and informatics networks
- Specimen resources
- Epidemiological resources pertaining to biology
- Reagents, chemical standards
- Education and training of investigators at all levels (including clinicians)

Etiology

- 2.1 Exogenous Factors in the origin and cause of cancer *Examples of science that would fit:*
 - Lifestyle factors such as smoking, chewing tobacco, alcohol consumption, parity, diet, sunbathing, and exercise
 - Environmental and occupational exposures such as radiation, second-hand smoke, radon, asbestos, organic vapors, pesticides, and other chemical or physical agents
 - Infectious agents associated with cancer etiology, including viruses (Human Papilloma Virus-HPV, etc.) and bacteria (*helicobacter pylori*, etc.)
 - Viral oncogenes and viral regulatory genes associated with cancer causation

2.2 Endogenous Factors in the origin and cause of cancer

Examples of science that would fit:

- Free radicals such as superoxide and hydroxide radicals
- Genes known to be involved or suspected of being mechanistically involved in familial cancer syndromes, e.g., BRCA1, Ataxia Telangiectasia, and APC
- Genes suspected or known to be involved in "sporadic" cancer events, for example polymorphisms and/or mutations that may affect carcinogen metabolism (e.g., CYP, NAT, glutathione transferase, etc.)

2.3 Interactions of Genes and/or Genetic Polymorphisms with Exogenous and/or Endogenous Factors

Examples of science that would fit:

- Gene-environment interactions
- Interactions of genes with lifestyle factors, environmental and/or occupational exposures such as variations in carcinogen metabolism associated with genetic polymorphisms
- Interactions of genes and endogenous factors such as DNA repair deficiencies and endogenous DNA damaging agents such as oxygen radicals or exogenous radiation exposure

2.4 Resources and Infrastructure Related to Etiology

- Informatics and informatics networks; for example patient databanks
- Specimen resources (serum, tissue, etc.)
- Reagents and chemical standards
- Epidemiological resources pertaining to etiology

- Statistical methodology or biostatistical methods
- Centers, consortia, and/or networks
- Education and training of investigators at all levels (including clinicians)

Prevention

- 3.1 Interventions to Prevent Cancer: Personal Behaviors that Affect Cancer Risk *Examples of science that would fit::*
 - Research on determinants of personal behaviors, such as diet, physical activity, sun exposure, and tobacco use, which affect cancer risk
 - Interventions to change personal behaviors that affect cancer risk
- 3.2 Nutritional Science in Cancer Prevention

Examples of science that would fit:

- Quantification of nutrients and micronutrients
- Studies on the effect(s) of nutrients or nutritional status on cancer incidence
- Dietary assessment efforts including dietary questionnaires and surveys
- Development, characterization and validation of dietary/nutritional assessment instruments

3.3 Chemoprevention

Examples of science that would fit:

• Chemopreventive agents and their discovery, mechanism of action, development, testing in model systems and clinical testing

3.4 Vaccines

Examples of science that would fit:

• Vaccines for prevention, their discovery, mechanism of action, development, testing in model systems and clinical testing

3.5 Complementary and Alternative Prevention Approaches

Examples of science that would fit:

- Discovery, development and testing of complementary/alternative prevention approaches such as diet, herbs, supplements or other interventions which are not widely used in conventional medicine or are being applied in different ways as compared to conventional medical uses
- Hypnotherapy, relaxation, transcendental meditation, imagery, spiritual healing, massage, biofeedback, etc., used as a preventive measure

3.6 Resources and Infrastructure Related to Prevention

- Informatics and informatics networks; for example patient databanks
- Specimen resources (serum, tissue, etc.)
- Epidemiological resources pertaining to prevention
- Clinical trials infrastructure
- Statistical methodology or biostatistical methods
- Centers, consortia, and/or networks

• Education and training of investigators at all levels (including clinicians)

Early Detection, Diagnosis and Prognosis

- 4.1 Technology Development and/or Marker Discovery *Examples of science that would fit:*
 - Discovery of markers (e.g., proteins, genes,) and/or technologies (such as fluorescence, nanotechnology, etc.) that are potential candidates for use in cancer detection, staging, diagnosis and/or prognosis
 - Use of proteomics, genomics, expression assays, or other technologies in the discovery of markers
- 4.2 Technology and/or Marker Evaluation with respect to Fundamental Parameters of Method *Examples of science that would fit:*
 - Development, refinement and preliminary evaluation (e.g., animal trials and Phase I human trials)
 - Preliminary evaluation with respect to laboratory sensitivity, laboratory specificity, reproducibility, and accuracy
 - Research into mechanisms assessing tumor response to therapy at a molecular or cellular level
- 4.3 Technology and/or Marker Testing in a Clinical Setting

- Evaluation of clinical sensitivity, clinical specificity and predictive value (Phase II or III clinical trials)
- Quality assurance and quality control
- Inter and intra-laboratory reproducibility
- Testing of the method with respect to effects on morbidity and/or mortality
- Study of screening methods including compliance, acceptability to potential screenees, receiver-operator characteristics
- Research into improvements in techniques to assess clinical response to therapy
- 4.4 Resources and Infrastructure Related to Detection, Diagnosis or Prognosis *Examples of science that would fit:*
 - Informatics and informatics networks; for example patient databanks
 - Specimen resources (serum, tissue, images, etc.)
 - Clinical trials infrastructure
 - Epidemiological resources pertaining to risk assessment, detection, diagnosis, or prognosis
 - Statistical methodology or biostatistical methods
 - Centers, consortia, and/or networks
 - Education and training of investigators at all levels (including clinicians)

Treatment

- 5.1 Localized Therapies Discovery and Development *Examples of science that would fit:*
 - Discovery and development of treatments administered locally that target the organ and/or neighboring tissue directly, including but not limited to surgical interventions and radiotherapy
 - Therapies with a component administered systemically but that act locally (e.g., photodynamic therapy, radioimmunotherapy and radiosensitizers)
 - Development of methods of drug delivery

5.2 Localized Therapies - Clinical Applications

Examples of science that would fit:

- Clinical testing and application of treatments administered locally that target the organ and/or neighboring tissue directly, including but not limited to surgical interventions and radiotherapy
- Clinical testing and application of therapies with a component administered systemically but that act locally (e.g., photodynamic therapy and radiosensitizers)
- Phase I, II or III clinical trials of promising therapies that are administered locally
- Side effects, toxicity and pharmacodynamics

5.3 Systemic Therapies - Discovery and Development

Examples of science that would fit:

- Discovery and development of treatments administered systemically such as cytotoxic or hormonal agents, novel systemic therapies such as immunologically directed therapies (vaccines, antibodies), gene therapy, angiogenesis inhibitors, apoptosis inhibitors and differentiating agents
- Defining molecular signatures of cancer cells
- Identifying molecular targets for drug discovery. Includes mechanistic studies of cellular metabolism, combinatorial chemical synthesis, drug screening, development of high throughput assays and testing in model systems
- Investigating the molecular mechanisms of drug resistance and pre-clinical evaluation of therapies to circumvent resistance
- Development of methods of drug delivery

5.4 Systemic Therapies - Clinical Applications

- Clinical testing and application of treatments administered systemically such as cytotoxic or hormonal agents, novel systemic therapies such as immunologically directed therapies (vaccines, antibodies), gene therapy, angiogenesis inhibitors, apoptosis inhibitors and differentiating agents
- Phase I, II or III clinical trials of promising therapies administered systemically
- Side effects, toxicity, and pharmacodynamics
- 5.5 Combinations of Localized and Systemic Therapies *Examples of science that would fit:*

- Development and testing of combined approaches to treatment
- Clinical application of combined approaches to treatment such as systemic cytotoxic therapy and radiation therapy

5.6 Complementary and Alternative Treatment Approaches *Examples of science that would fit:*

• Discovery, development, and clinical application of complementary/alternative treatment approaches such as diet, herbs, supplements, natural substances or other interventions which are not widely used in conventional medicine or are being applied in different ways as compared to conventional medical uses

5.7 Resources and Infrastructure Related to Treatment

Examples of science that would fit:

- Informatics and informatics networks; for example clinical trial networks and databanks
- Mathematical and computer simulations
- Specimen resources (serum, tissue, etc.)
- Clinical trial groups
- Epidemiological resources pertaining to treatment
- Statistical methodology or biostatistical methods
- Drugs and reagents for distribution and drug screening infrastructures
- Centers, consortia, and/or networks
- Education and training of investigators at all levels (including clinicians)

Cancer Control, Survivorship and Outcomes Research

6.1 Patient Care and Survivorship Issues

Examples of science that would fit:

- Quality of life
- Pain management
- Psychological impacts of cancer survivorship
- Rehabilitation
- Reproductive issues
- Long term morbidity
- Symptom management, including nausea, vomiting, lymphedema, neuropathies etc.
- Prevention of treatment related toxicities and sequlae including symptom management, prevention of mucosities, prevention of cardiotoxicities, etc.

6.2 Surveillance

- Epidemiology and End Results Reporting (e.g., SEER)
- Surveillance of cancer risk factors such as diet, body weight, physical activity, sun exposure, tobacco use
- Analysis of variations in risk factor exposure by demographic or other factors
- Registries which track incidence, morbidity and/or mortality related to cancer
- Trends in use of interventional strategies
- Method development for risk factor surveillance

6.3 Behavior

Examples of science that would fit:

- Behavior medicine research and interventions
- Influence of social factors, such as, community, policy, education, and legislation, on behaviors related to cancer control
- Attitudes and belief systems and their influence on psychological health and on behaviors related to cancer control (For example, how beliefs can alter attempts to seek screening, detection, and treatment)
- Interventions to change attitudes and beliefs that affect behavior related to cancer control and cancer outcomes
- Influences of attitudes and beliefs on compliance to treatment and prevention protocols
- Psychological or educational interventions to promote behaviors that lessen treatmentrelated morbidity and promote psychological adjustment to the diagnosis of cancer and to treatment effects
- Burdens of cancer on family members/caregivers and psychological/behavior issues

6.4 Cost Analyses and Health Care Delivery

Examples of science that would fit:

- Analyses of cost effectiveness of methods used in cancer prevention, detection, diagnosis, prognosis, treatment, and survivor care/support
- Development and testing of health service delivery methods
- Interventions to increase the quality of health care delivery
- Impact of organizational, social, and cultural factors on access and quality of care
- Studies of providers, such as geographical or care-setting variations in outcomes
- Effect of reimbursement and/or insurance on cancer control, outcomes and survivorship support
- Access to care issues
- Health services research including health policy and practice
- Analysis of health service provision, including the interaction of primary and secondary care; cost effectiveness of treatments

6.5 Education and Communication

- Development of communication tools and methods
- Education of patients, health care providers, at-risk populations, and general population about cancer
- Communication to patients regarding therapeutic options
- Educational interventions to promote self-care and symptom management
- Communicating cancer risk to underserved populations, at-risk populations, and the general public
- Alternative teaching methods to communicate therapeutic options and risk reduction behavior to patients or the general public
- Communication of lifestyle models that reduce cancer risk, such as communication of nutrition interventions
- Communicating smoking and tobacco cessation interventions
- Special approaches and considerations for underserved and at-risk populations

- Education, information, prevention/screening/assessment systems for the general public, primary care professionals or policy makers
- Training, predictive cancer models, pain management, and surveillance systems for primary care professionals, telehealth/telemedicine applications
- Communication regarding cancer genetics, managed oncology care, communicating with survivors
- Barriers to successful health communication

6.6 End of Life Care

Examples of science that would fit:

- End of Life Care issues including palliative care, psychological interventions with families at end of life, hospice care, pain management for terminally ill patients, etc.
- 6.7 Ethics and Confidentiality in Cancer Research

Examples of science that would fit:

- Informed consent modeling and development
- Quality of Institutional Review Boards (IRB)
- Protecting patient confidentiality and privacy
- Research ethics
- 6.8 Complementary and Alternative Approaches for Supportive Care of Patients and Survivors *Examples of science that would fit:*
 - Hypnotherapy, relaxation, transcendental meditation, imagery, spiritual healing, massage, biofeedback, etc., as used for the supportive care of patients and survivors
 - Discovery, development and testing of complementary/alternative approaches such as diet, herbs, supplements or other interventions that are not widely used in conventional medicine or are being applied in different ways as compared to conventional medical uses
- 6.9 Resources and Infrastructure Related to Cancer Control, Survivorship and Outcomes Research *Examples of science that would fit:*
 - Informatics and informatics networks
 - Clinical trial groups related to cancer control, survivorship, and outcomes research
 - Epidemiological resources pertaining to cancer control, survivorship, and outcomes research
 - Statistical methodology or biostatistical methods
 - Surveillance infrastructures
 - Centers, consortia, and/or networks
 - Education and training of investigators at all levels (including clinicians)
 - Psychosocial, economic, political and health services research frameworks and models

Scientific Model Systems

7.1 Development and Characterization of Model Systems

Examples of science that would fit:

Development and characterization of model systems, including but not limited to:

• Computer simulation model systems and computer software development

- In vitro models systems
- Cell culture model systems
- Organ and tissue model systems
- Animal model systems such as drosophila and c. elegans, zebra fish, mouse, etc.

7.2 Application of Model Systems

Examples of science that would fit:

Application of model systems, including but not limited to:

- Computer simulation model systems and computer software development
- In-vitro models systems
- Cell culture model systems
- Organ and tissue model systems
- Animal model systems such as drosophila and c. elegans, zebra fish, mouse, etc.

7.3 Resources and Infrastructure Related to Scientific Model Systems

- Models made available for distribution to the scientific community
- Centers, consortia, and/or networks
- Education and training of investigators at all levels (including clinicians)

APPENDIX B: SAMPLES OF GENERAL AUDIENCE SUMMARIES

1. Clinical and Epidemiology Research

Title: Characterization of Early Breast Cancer by Contrast-Enhanced MRI

Magnetic resonance imaging (MRI) shows great promise as a supplementary tool to mammography and clinical exam for diagnosis and staging of breast cancer. Most research in this area has focused on diagnosis of invasive breast cancer. We have been interested in improving the ability of MRI to characterize early cancer, particularly at the pre-invasive stage. At the present time, the accuracy of MRI to for diagnosing pre-invasive breast disease, or ductal carcinoma in situ (DCIS) is low, mainly because the pattern of contrast enhancement for DCIS is difficult to distinguish from that of benign proliferative disease in the breast. An important emerging application for MRI is screening and surveillance in women at increased risk of developing breast cancer. There are now genetic tests and statistical models that can accurately predict a woman's risk. However, there are few effective options for prevention and early detection. Women with a genetic risk of developing cancer are also likely to develop cancer at an early age when breast tissue is dense and mammography effectiveness is limited. MRI is very sensitive to small cancers and not limited by breast density. The studies we propose will address the specificity of MRI for early cancer and will have direct application to MRI screening and surveillance methods. We believe that in the future, a better understanding of the biological basis of patterns on MRI may lead to new methods for identifying breast tissue that is at risk for developing cancer.

2. Cancer Control and Prevention Research:

Title: Distrust as a Barrier to Cancer Screening and Prevention

Over the past 40 years technological advancements have had a major impact on medicine in the United States. These advancements have lead to the development of effective methods in cancer screening and, most recently, cancer prevention. These methods have the potential to greatly reduce the burden of cancer, but are being threatened by the rising levels of distrust of physicians and the health care system. This project will investigate the issue of distrust with the goals of increasing understanding of health care related distrust in the US today and investigating the relationship between health care related distrust and attitudes, intentions, and behaviors regarding cancer screening and prevention.

We will focus on a population composed of African American, Caucasian, and Hispanic women to elucidate the relationship between health care related distrust and historically disadvantaged ethnic/racial minorities. These women will be between the ages of 40 and 70, a group for whom effective cancer screening is available and recommended. In order to determine the patterns of health care related distrust and association between distrust and attitudes towards cancer screening and prevention, we will conduct a population-based telephone survey in the United States. We will examine several types of cancer related health behaviors and investigate how distrust may act as a barrier to adopting these behaviors. These behaviors will include adherence

with current cancer screening recommendations for breast, cervical and colon cancer as well as willingness to use new interventions for cancer screening and prevention.

This project builds upon our prior work that has provided a more in-depth understanding of health care related distrust and established the association between health care related distrust and use of PAP smear, clinical breast examination, and influenza vaccination in the City of Philadelphia. This grant will allow us to identify the factors and beliefs the population may have about health care and physicians and determine what role distrust plays as a barrier to cancer screening and prevention. These findings will have the direct potential to improve the delivery of effective cancer screening and prevention behaviors.

3. Basic Research:

Title: Regulation of Chromosome Segregation in Human Cells

The information which controls all of the operations of a cell is contained within its DNA, which is packaged into units called chromosomes. When a cell divides, these chromosomes must be duplicated. During duplication each chromosome is connected to its copy, therefore, the duplicated chromosomes must be properly unlinked from one another, so that each new cell receives or inherits exactly the same genetic information as all of the other cells. Errors in this process, known as chromosome segregation, result in extra chromosomes in some cells and too few chromosomes in others. Such errors are widespread among most cancer cells, and are believed to promote the growth and progression of disease. Our long term goal is to understand the molecules and mechanisms that control chromosome segregation in human cells. Towards this aim, we have begun to analyze a critical enzyme, appropriately named separase, that functions like a "molecular scissors" to split apart linked chromosomes as cells prepare to divide. Separase acts irreversibly in this process and thus needs to be controlled very precisely, to avoid potentially catastrophic errors. In this proposal, we will investigate the ways in which separase is turned on and turned off during cell division. Using a series of complementary approaches, including a novel method we invented several years ago for manipulating genes inside human cells, we will define how the chromosome-splitting process is controlled at the molecular level, and how that control ensures the high level of accuracy of chromosome segregation. Ultimately, we hope to translate this knowledge into new strategies for detecting and eliminating cells that cannot segregate their chromosomes accurately, before they have the opportunity to develop into cancers.

APPENDIX C: SAMPLE OF STRUCTURED TECHNICAL ABSTRACT

Title of Project: Structure and Function of DNA Replication Origins in Yeast

Background: The initiation of DNA replication marks a crucial step in the eukaryotic cell cycle. Entering S phase commits the cell to a full round of cell division. Studies in the budding yeast, *Saccharomyces cerevisiae*, have driven the field during the past decade, although our data and work by others suggest that many aspects of DNA replication are highly conserved in all eukaryotes, including humans. Origin structure has been best described for autonomously replicating sequence (ARS) function. Different origins have a different domain organization, and it is unclear how these differences impact the initiation of DNA replication. Recently, we have shown that initiation events occur at distinct nucleotide positions in yeast, a feature that appears to be conserved in humans.

Objective/Hypothesis: Our preliminary studies indicate that origin organization dictates where replication initiates. Therefore, we propose to define how features of ARS elements contribute to the precise initiation mechanism.

Specific Aims: (1) To determine whether chromosomal origins other than ARS1 initiate DNA replication at a distinct site; (2) to identify what determines the replication start point within origins; and (3) to determine if chromatin structure affects the initiation pattern at ARS elements.

Study design: Using a technique that we have recently developed, replication initiation point mapping, we will first map the nucleotide positions at which replication initiates in wild-type and mutant ARS elements. To address the issue of what role chromatin configuration plays in origin activation, we will analyze the nucleosomal organization of different ARS loci in relation to those regions where the parental DNA double-strand unwinds first. We will correlate the sites of initiation with sites of unwinding and place those into context with the overall chromatin structure at a given chromosomal ARS locus.

Cancer relevance: These studies will contribute to our understanding of the mechanism underlying origin activation in yeast and will aid us in understanding origin function in more complex, higher eukaryotes. Since uncontrolled origin activity directly translates into uncontrolled growth, the long-term goal of our studies is to apply our knowledge and techniques to human DNA replication in order to inhibit proliferation of cancerous cells.

APPENDIX D: SAMPLE OF TABLE OF CONTENTS

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