

AMERICAN CANCER SOCIETY
PILOT AND EXPLORATORY PROJECTS
IN PALLIATIVE CARE OF CANCER PATIENTS AND THEIR FAMILIES

POLICIES AND INSTRUCTIONS

EFFECTIVE JULY 2019

ELECTRONIC APPLICATION DEADLINE: OCTOBER 15, 2019

PAPER APPLICATION COPY DEADLINE: OCTOBER 16, 2019

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**Applicants are strongly advised to verify their eligibility prior to preparing an application.
Applications that do not comply with eligibility criteria will be administratively
disapproved. Complete requirements and instructions are included in this document.**

MISSION

**The American Cancer Society's mission is to save lives, celebrate lives, and lead the fight
for a world without cancer.**

PILOT AND EXPLORATORY PROJECT

POLICIES

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

The American Cancer Society's Extramural Research Program primarily supports beginning investigators, across a wide range of disciplines, in innovative cancer-control research and training to meet critically important needs in the control of cancer.

Each year the Society receives approximately 1,500 grant requests. All undergo rigorous, independent peer review to identify the most meritorious projects for funding.

The Society offers extramural support for research and training via the programs described below. For program-specific information, please see Section 20.

GRANT MECHANISMS

RESEARCH GRANTS FOR INDEPENDENT INVESTIGATORS

Research Scholar Grants provide resources for investigator-initiated research projects in a variety of cancer-relevant areas.

- **Eligibility**

Applicants must be independent, self-directed researchers within 6 years of their first academic appointment. Clinician scientists who remain active in patient care must be within eight years of their first academic appointment. Applicants typically must be within 12 years of receiving a terminal (doctorate) degree and cannot have more than one R01/R01-like grant (>\$100,000 per year direct costs for more than three years) as principal investigator at the time of application.

RSG applicants to **ONLY** the Cancer Control and Prevention Research Program may be at any career stage, provided that the focus of their project is either: 1) health policy/health services research or 2) achieving cancer health equity. These applicants must also meet the RSG eligibility requirements (described above).

- **Funding**

The maximum award covers four years with up to \$165,000 per year (direct costs), plus 20% allowable indirect costs. Additionally, population-based studies that address cancer health equity may propose up to a maximum of five years and \$400,000 per year (direct costs), plus 20% allowable indirect costs.

For the RSG award in the Cancer Control and Prevention Research Program with a focus on health disparities or health policies/services, the maximum award is for four years at up to \$200,000 per year (direct costs), plus 20% allowable indirect costs.

Institutional Research Grants (IRG) are awarded to institutions as block grants, providing seed money for newly independent investigators to initiate cancer research projects.

- **Eligibility**

The principal investigator of the grant, who will also serve as the chair of the local IRG Committee, should be a senior faculty member.

- **Funding**

Grants to institutions cover one to three years, average \$120,000 per year and may be renewed.

Mission Boost Grants (MBG) are opportunities for ACS grantees to seek additional (“boost”) resources for innovative high-risk/high-reward projects. MBGs potentially offer two stages of funding.

The *Primary Boost* requires the investigator to develop outcome-specific, unequivocal milestones that reduce the risks of studying a new drug, device, or procedure in patients.

- **Eligibility**

Current and former ACS grantees with innovative projects who:

- Have held or currently hold one of these grants (or previous versions of such awards): Research Scholarship Grant (RSG), Mentored Research Scholar Grant (MRSRG), Cancer Control Career Development Awards (CCCCA), or Pilot and Exploratory Projects in Palliative Care (PEP) award.
- Have held one of the above ACS grants for a minimum of one year. Note: For current ACS grantees, we recommend delaying submission of letter of intent (LOI) until the last year of the grant, since part of the LOI review may include consideration of discoveries made under ACS support; and
- Are currently independent, full-time faculty at a not-for-profit, US-based research institution that has facilities and support to enable preclinical and clinical studies.

- **Funding**

A maximum of \$100,000 direct, plus 20% indirect costs per year and may be requested for up to two years (Total: \$240,000).

The *Secondary Boost* supports testing in cancer patients.

- **Eligibility**

Only MBG recipients who have completed and submitted Primary Boost milestones for approval.

- **Funding**

A maximum of \$300,000 direct plus 20% indirect costs (Total: \$360,000) and may be requested for up to 18 months.

Pilot and Exploratory Projects in Palliative Care of Cancer Patients and their Families

support investigators performing such research studies to 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.

- **Eligibility**

Investigators in areas of palliative care.

- **Funding**

The maximum award is for two years and up to \$60,000 per year (direct costs) plus 20% indirect costs.

MENTORED TRAINING GRANTS

Postdoctoral Fellowships fund training for a career in cancer research for researchers with a doctoral degree.

- **Eligibility**

Researchers who are US citizens or permanent residents and within four years of receiving a doctoral degree.

- **Funding**

Awards may cover up to three years with progressive stipends of \$48,000, \$50,000, and \$52,000 per year, plus a \$4,000 per year fellowship allowance. In addition, \$1,500 will be provided in the last year for travel costs, either to the biennial ACS Jiler Professors and Fellows Conference or to another scientific meeting in the US.

Clinician Scientist Development Grants support protected time to allow junior faculty who see patients to be mentored and participate in research training, thus aiding their development as independent clinician scientists. These investigators pursue questions relevant to improving health across the cancer research continuum.

- **Eligibility**

Applicants must be full-time faculty and within the first six years of their initial appointment. They must have a clinical doctoral degree with an active license to provide patient care and actively seeing patients.

- **Funding**

Awards range from three to five years and 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) may be included in the \$135,000.

HEALTH PROFESSIONAL TRAINING GRANTS

Physician Training Awards in Cancer Prevention are reserved for institutions. They support physician training in accredited preventive medicine residency programs that provide cancer prevention and control research and practice opportunities.

- **Eligibility**

Applications are generally submitted by the program director from accredited general preventive medicine or occupational and environmental residency programs.

- **Funding**

Awards cover four and one half years with a total amount of \$300,000, based on an average of \$50,000 per resident training year. These grants are renewable.

Doctoral Training Grants in Oncology Social Work support doctoral students conducting research related to oncology social work.

- **Eligibility**

Students with a master's degree in social work enrolled in a doctoral program in an accredited school of social work.

- **Funding**

Initial two-year grants provide a stipend of \$20,000 per year with the possibility of a two-year renewal.

Master's Training Grants in Clinical Oncology Social Work, awarded to institutions, support training for second year master's degree students in oncology social work.

- **Eligibility**

Applicants are MSW-prepared field instructors at clinical placement sites that are affiliated with accredited schools of social work with health care or mental health care concentrations and provide students the opportunity to concentrate in pediatric or adult oncology.

- **Funding**

The grant term is two years with annual funding of \$12,000 (up to \$10,000 for the student \$2,000 for faculty professional development). These grants can be renewed.

Doctoral Degree Scholarships in Cancer Nursing support study in a doctoral degree program in nursing or a related area, preparing the graduate for a career as a cancer nurse scientist.

- **Eligibility**

Licensed registered nurses enrolled in an accredited academic institution that can award a doctoral degree.

- **Funding**

The initial award is for two years and \$15,000 per year; it may be renewed for an additional two years.

Graduate Scholarships in Cancer Nursing Practice support graduate students pursuing a master's degree in cancer nursing or a doctorate of nursing practice.

- **Eligibility**

Licensed registered nurses applying to or enrolled in accredited schools of nursing.

- **Funding**

Awards may be for up to two years with a stipend of \$10,000 per year.

PROFESSOR AWARDS

Professor Awards provide unique research opportunities that foster creativity and innovation in cancer research. Professor Awards provide flexible funding for outstanding individuals who have made seminal contributions that have changed and will continue to change the direction of cancer or cancer control research.

Research Professor Awards support outstanding mid-career investigators in cancer research.

Clinical Research Professor Awards support outstanding mid-career investigators in areas of clinical, psychosocial, behavioral, health policy, or epidemiologic cancer research.

- **Eligibility**

Applicants for either award must have attained the rank of full professor, but for no more than 15 years at this rank. The annual deadline is October 15 for Clinical Research Professor Awards or April 1 for Research Professor Awards.

- **Funding**

Both awards are for five years at \$80,000 per year, in the total amount of \$400,000 in unrestricted funds, and may be renewed once.

INTERNATIONAL PROGRAM

Audrey Meyer Mars International Fellowships in Clinical Oncology support one year of advanced training in clinical oncology at participating United States (US) cancer centers.

- **Eligibility**

Non-US citizens—qualified physicians and dentists from other countries, particularly those where advanced oncology training is not readily available.

- **Funding**

This program provides up to US \$65,000 for one year.

REQUESTS FOR APPLICATION (RFAs)

Research Scholar Grant in the Role of Health Policy and Healthcare Insurance in Improving Access to Care and Performance in Cancer Prevention, Early Detection, and

Treatment Services supports investigations evaluating the impact of changes occurring in the health care system with a focus on cancer prevention, control, and treatment.

Improving access to care may also reduce inequities and health disparities. New health public policy initiatives—for example, the new federal and state marketplaces that have expanded insurance coverage, as well as Medicaid expansion in some states—create natural experiments ripe for evaluation. Research funded by this RFA focuses on the changes in national, state, and/or local policy and the response to these changes by health care systems, insurers, payers, communities, practices, and patients.

Applications will be accepted via the Research Scholar Grant in Cancer Control and Prevention Program.

- **Eligibility**

Investigators evaluating changes in the health care system with a focus on cancer.

- **Funding**

Award length and budget limits vary; please see the Research Scholar Grant policies and instructions for a detailed description of this RFA.

SPECIAL INITIATIVE

PRIORITY FOCUS ON HEALTH EQUITY RESEARCH IN THE CANCER CONTROL AND PREVENTION RESEARCH GRANTS PROGRAM

Despite the steady overall decline in cancer incidence and mortality rates in the United States, not all population groups have benefited equally. Differences exist among subgroups in rates of incidence, prevalence, mortality, and related adverse health conditions. As highlighted in reports by the Agency for Healthcare Research and Quality and the Institute of Medicine, health disparities are linked to interrelated risk factors that extend across the life span (Braveman, 2014).

However, if the existing knowledge about cancer prevention, early detection, and treatment were delivered equally, disparities in cancer could be substantially reduced or eliminated. Achieving health equity through inclusive health and social systems, in which all people are treated equitably, creates conditions for improving health outcomes.

The American Cancer Society (ACS) has a long and ongoing history of advocacy, education, community outreach, and research in the area of cancer disparities.

Social determinants of health include environmental conditions—the influence of the world in which people are born, live, play, thrive, work and worship—and the availability of health care systems. The economic, political and social policies that shape communities are integral to these influences.

Individual determinants of health include biology, genetics, and individual behaviors and characteristics. Health disparities are related to age, gender, disability status, ethnicity, race,

geography, income, language, social class, or sexual orientation. The National Stakeholder Strategy for Achieving Health Equity, supported by the U.S. Department of Health and Human Services Office of Minority Health, presents an action-oriented blueprint to move the nation towards achieving health equity, by combating health disparities with a comprehensive, community-driven approach. The ACS has overlapping goals and is committed to addressing cancer health equity through research, education, advocacy, and service.

The ACS Extramural Research and Training Grants Department identifies research addressing health equity as a priority, and RSG grant applications to its Cancer Control and Prevention Research Program are welcome from principal investigators at any career stage. These should focus on eliminating disparities through either psychosocial and behavioral research, or in health policy and health services research.

This expanded eligibility is unique to projects Targeting Health Equity and Health Disparities in Cancer Prevention and Control. Applicants must explicitly specify the following within the application:

- relevance to cancer generally and cancer disparities specifically;
- how findings from the proposed research will substantially improve equity in access to cancer prevention, early detection, diagnosis, and/or treatment services; and
- how findings may be applied to more quickly advance efforts to reduce cancer burden or costs, improve quality of care or quality of life, and/or save more lives.

All cancer health-equity applications must target two or more determinants of health. Population-based health equity studies must also target two or more levels of influence (individual, interpersonal, organizational, community, or public policy) to propose interventions focused on achieving health equity. (McLeroy et al., 1988; CDC, 2014).

Applications will be accepted using one of four mechanisms:

- Postdoctoral Fellowship
- Clinician Scientist Development Grant
- Research Scholar Grant
- Clinical Research Professor Award

References:

Braveman P. What Are Health Disparities and Health Equity? We Need to Be Clear. *Nursing in 3D: Diversity, Disparities, and Social Determinants*. Public Health Reports. 2014 Supplement 2; 129:1-8

McLeroy KR1, Bibeau D, Steckler A, Glanz K. An ecological perspective on health promotion programs. *Health Educ Q*. 1988; 15(4):351-77.

Centers for Disease Control and Prevention (CDC). Colorectal Cancer Control Program: Social Ecological Model. Available at: <http://www.cdc.gov/cancer/crccp/sem.htm>

GRANT PROGRAM OFFICES

HEALTH PROFESSIONAL TRAINING IN CANCER CONTROL — Virginia Krawiec, MPA, Scientific Director

This program supports nurses, physicians, and social workers pursuing training in cancer prevention and control practice. The goal is to accelerate the wide application of research findings by increasing the number of these professionals with expertise and career commitment to cancer control.

MOLECULAR GENETICS AND BIOCHEMISTRY OF CANCER — Michael Melner, PhD, Senior Scientific Director

This program focuses on genes involved in cancer and the role their alterations (mutations, deletions, and amplifications) play in the process. Of particular interest is the examination of the molecules involved in cancer (proteins, nucleic acids, lipids, and carbohydrates) and how their activities affect these diseases. The program highlights new targets for prevention, detection, and treatment of cancer.

CANCER CELL BIOLOGY AND METASTASIS — Charles Saxe, PhD, Senior Scientific Director

The primary goal of this program is to provide an understanding of the nature of cancer cells, so they can be more effectively controlled 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; how cells relate to the local environment and to other cells; and how cells regulate when and how to move from one site to another.

TRANSLATIONAL CANCER RESEARCH — Lynne Elmore, PhD, Scientific Director

This program focuses on the interface between laboratory investigations and human testing. The program supports investigations of the role of the microbiome and infectious diseases in cancer; microbial-based cancer therapies; the discovery, synthesis, and delivery of cancer drugs; the creation and use of animal models of cancer; and biomarker identification/development.

CLINICAL CANCER RESEARCH, NUTRITION, AND IMMUNOLOGY — Susanna Greer, PhD, Scientific Director

This program focuses on therapies for cancer. It includes basic, preclinical, clinical, and epidemiological investigations of immunotherapy, inflammatory responses, immunosurveillance, and innate and adaptive immune responses. Emphases include development and application of new imaging and bioanalytical tools and techniques, and how the exposome, nutrition, physical activity, and environment impact cancer prevention, initiation, progression, and treatment.

CANCER CONTROL AND PREVENTION RESEARCH — Elvan C. Daniels, MD, MPH, Scientific Director

This program focuses on the development and testing of interventions to influence health behaviors and health-care delivery. Research projects in this program focus on cancer risk

reduction and delivery of high-quality health promotion, screening, early detection, and treatment services. The program also includes projects directed at health services, outcomes, and policy research to assess the effectiveness of interventions and the impact of policies on access to care, quality of care, and costs of care. Special emphasis is placed on health-equity research addressing disparities in disadvantaged groups and the social determinants of health that drive inequities.

2. AUTHORITY FOR MAKING GRANTS

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

3. SOURCE OF FUNDS

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

4. WHO MAY APPLY

Applicants for the Clinician Scientist Development Grant and Postdoctoral Fellowships must be, at the time of application, United States citizens, or permanent residents. There are no citizenship requirements for any other grants.

The Society will allow only one designated individual as principal investigator, responsible and accountable for the overall conduct of the project; the Society does not recognize co-principal investigators.

Although applicants may apply for multiple awards, a grantee may not be the principal investigator on more than one ACS grant at any time. Exceptions are made for recipients of grants in response to RFAs and for principal investigators of Institutional Research Grants, Mission Boost Grants or TheoryLab pilot projects.

5. TOBACCO-INDUSTRY FUNDING POLICY

Scientific investigators or health professionals who are funded for any project by the tobacco industry, or whose named mentors are so funded, are not eligible for American Cancer Society (ACS) grants. Any of these who accept tobacco-industry funding during the term of a grant must inform the Society, whereupon the grant will be terminated.

Tobacco industry funding includes:

- Funds from a company that is engaged, or whose affiliates are 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; and

- Funds from a body set up by the tobacco industry or by 1 or more companies in the industry.

The following do not constitute tobacco industry funding:

- Legacies funds from tobacco industry investments (unless the name of a tobacco company or cigarette brand is associated with them);
- Funds from a trust or foundation established with assets related to the tobacco industry, but which no longer have any connection with the industry, even though the entity 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 any costs for research, including personnel, consumables, equipment, buildings, travel, meetings, and conferences, or operating costs for laboratories and offices. It does not include meetings or conferences unrelated to a particular research project.

6. COLLABORATIONS WITH ACS INTRAMURAL SCIENTISTS (IF APPLICABLE)

- 1) If an extramural scientist is planning a collaboration with an ACS intramural scientist, and they meet all other requirement of eligibility, they may be eligible to submit an application. Such collaborations are not required.
- 2) In most cases, the use of ACS research resources requires that at least one ACS intramural scientist be included as a collaborator on a grant application. Therefore, prior to submission of an application, the collaboration between extramural scientists and intramural scientists must be established according to the policies and procedures of ACS Intramural Research.
- 3) Intramural scientists and their staff may participate in grants and contracts in many ways, including:
 - Serving as unpaid consultants, collaborators, co-investigators, or mentors. Intramural scientists may not serve as a principal investigator on an ACS grant or contract.
 - Contributing to the conceptualization, design, execution, or interpretation of a research study.
 - Having primary responsibility for a specific aim within a standard research grant mechanism.
 - Developing or contributing data for an extramural collaboration.
 - Participating in a multi-institutional collaborative arrangement with extramural researchers for clinical, prevention, or epidemiological studies.
- 4) ACS intramural scientists may not receive salary support, travel expenses, or other funds from ACS-funded grants or contracts.
- 5) Intramural and extramural scientists may have access to reagents, laboratory equipment, and/or data to conduct the extramurally funded portion of the research, as established in their collaborative agreement.
- 6) While intramural scientists may write a description of the work to be performed by the intramural department, they may not write an applicant's grant application or contract

proposal. However, the intramural scientist(s) should review and approve sections relevant to the collaboration.

- 7) ACS intramural scientist participation must comply with disclosure, non-disclosure, and conflict-of-interest regulations.
- 8) ACS intramural scientists must file annual and final research reports related to their activities associated with any grant or contract awarded through the Extramural Research Department.

¹Adapted from document NIH Policy 54815 Implementation of Cooperative Agreement, “Funding of Intramural Research Program/Extramural Research Program Collaborations” [<http://sourcebook.od.nih.gov/ethic-conduct/fund-irp-erp-3-00.htm>], and “Opportunities and Guidelines to Facilitate Scientific Collaborations” [<http://www.niaid.nih.gov/researchfunding/grant/Pages/extraintracollab.aspx>]

7. ELIGIBLE INSTITUTIONS AND INSTITUTIONAL RESPONSIBILITIES

The Society’s grants and awards are made to not-for-profit institutions located within the United States and its territories. A not-for-profit institution is one that can provide upon request:

- A current letter from the Internal Revenue Service conferring 501(c)(3) status;
- Evidence of an active research program with a track record of extramural funding and publications in peer reviewed journals; and
- Documentation of appropriate resources and infrastructure to support the proposed research. These include, but are not limited to:
 - Adequate facilities and services;
 - Fiscal and grants management infrastructure to ensure compliance with ACS policies, and with federal policies regarding protections for human and animal subjects (e.g., a sponsored-projects office or a contract with an IRB or IACUC);
 - A process for appointment and promotion equivalent to those in academic settings for staff scientists; and
 - Evidence of education, training, and mentoring for fellows and beginning researchers appropriate to the grant mechanism.

Grant applications will not be accepted, nor will grants be made, for research conducted at

- For-profit institutions;
- Federal government agencies (including the National Laboratories);
- Organizations supported entirely by the federal government (except postdoctoral fellowship applications);
- Organizations that primarily benefit federal government entities, such as foundations operated by or for the benefit of Veterans Affairs Medical Centers (VAMC). However, qualified academic institutions may submit applications on behalf of a VAMC if a Dean’s Committee Memorandum of Affiliation is in effect between the 2 institutions.

The American Cancer Society does not assume responsibility for the conduct of the activities that the grant supports, or for the acts of the grant recipient, because both are under the direction and control of the grantee institution and subject to its medical and scientific policies.

Every grantee institution 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 of the US Department of Health and Human Services.

Furthermore, applicants, applicant institutions, and grantee institutions must adhere to DHHS guidelines as well as ACS guidelines regarding conflicts of interest, recombinant DNA, scientific misconduct, as well as all other applicable ACS policies and procedures.

To signify agreement by the institution to all ACS policies and procedures, an application for a grant must bear the signatures of the official authorized to sign for the institution and the appropriate department head. Additional signatures are at the discretion of the institution.

The institution is responsible for verifying that all documentation related to the application and grant is correct, including all representations made by any named researcher (e.g. position or title). Further, the institution is responsible for verifying that the applicant is either a US citizen or permanent resident with a Resident Alien Card (“Green Card”) where applicable. If the award does not require US citizenship or permanent residency, the institution is responsible for documenting the applicant’s legal eligibility to work in the US for the duration of the award. For postdoctoral fellowships, if the terminal degree is granted after submission of the application, the institution must verify that the degree has been awarded prior to grant activation.

It is the responsibility of the institution to immediately report to ACS any finding that any information presented to ACS in connection with the application and/or grant was false. It is also the responsibility of the institution to immediately report to ACS any action including recertification, loss of certification, breach of contract, misconduct, or change in employment status for a named researcher with the institution. This includes administrative leave, which may occur during the term of any award pertinent to the work described in the grant application.

Failure to abide by the terms above, or by any other ACS policy or procedures, may result in suspension or cancellation of the grant, at the sole discretion of ACS.

By accepting an American Cancer Society award, you agree to the Guidelines for Maintaining Research and Peer Review Integrity found in the appendix of these policies.

8. PEER REVIEW OF APPLICATIONS

The Society's scientific directors distribute applications to the most appropriate peer review committee, and then assign each application to at least 2 committee members for independent and confidential review. Each committee generally has between 12 and 25 members who are leaders in their areas of expertise, plus up to 3 other 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 a personal experience with the disease, such as survivorship, a family cancer experience, or caregiving.

Peer review committees use application evaluation criteria that vary depending on the grant mechanism. See individual instructions for details.

After the peer review committee discusses and votes to prioritize the most competitive applications, it provides its recommendations, along with critiques of the applications and fundable scores, to the Council for Extramural Research.

After considering the relative merit of the applications, the amount of available funds, and the Society’s objectives, the Council determines which grants will be funded during each cycle. No voting member of a peer review committee or of the Council may be a member of the Society’s staff or Board of Directors.

In general, applications for research grants that are not funded may be revised and resubmitted twice; postdoctoral fellowship applications may only be resubmitted once. Resubmitted applications are reviewed in the same detail as new applications and compete with them on an equal basis. (See instructions for resubmission of applications.)

9. APPLICATION DEADLINES

Applications for grants and awards must be submitted as paper and electronic copies via proposalCENTRAL on the American Cancer Society website www.cancer.org (see Instructions). The electronic applications must be submitted by 5:00 PM ET on the specified deadline date, and a paper copy is due one business day later. If the deadline falls 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 ACS staff or reviewers.

DEADLINE, REVIEW, NOTIFICATION, AND ACTIVATION SCHEDULE

GRANTS	Application* Deadline	Peer Review Meeting	Preliminary Notification	Council Meeting	Grantee Notification	Activation
Research Scholar Grant	April 1 October 15	June January	August March	September March	October April	January 1 July 1
Mentored Research Scholar Grant	DISCONTINUED; See Clinician Scientist Development Grant					
Clinician Scientist Development Grant	April 1 October 15	June January	August March	September March	October April	January 1 July 1
Postdoctoral Fellowship	April 1 October 15	June January	August March	September March	October April	January 1 July 1
Pilot and Exploratory Projects	April 1 October 15	June January	August March	September March	October April	January 1 July 1
Institutional Research Grant	April 1	June	August	September	October	January 1

Physician Training Award in Cancer Prevention	April 1	June	August	September	October	January 1
Research Professor Award	LOI Deadline: February 1	June	NA	September	October	January 1
	Application Deadline: April 1					
Clinical Research Professor Award	LOI Deadline: August 1	January	NA	March	April	July 1
	Application Deadline: October 15					
Mission Boost Grant	LOI Deadline: March 1	August	September	September	October	January 1
	Application Deadline: July 15					
Doctoral Training Grant in Oncology Social Work	Application Deadline: October 15	January	March	March	April	July 1
Master's Training Grant in Clinical Oncology Social Work	October 15	January	March	March	April	July 1
Cancer Control Career Development Award	DISCONTINUED; See Clinician Scientist Career Development Grant					
Doctoral Degree Scholarship in Cancer Nursing	October 15	January	March	March	April	July 1
Graduate Scholarship in Cancer Nursing Practice	November 1	January	March	March	April	July 1
Audrey Meyer Mars International Fellowships in Clinical Oncology	October 15	January	March	March	April	July 1

***Paper copy is due one business day following the deadline for the electronic copy.**

10. NOTIFICATION OF APPLICATION RECEIPT AND REVIEW

Approximately one month after receipt of the application, applicants will receive an email acknowledgment providing an application number, the assigned peer review committee, and the name of their Scientific Director with contact information. This email will be sent to the address in the professional profile supplied at the time of submission in proposalCENTRAL. Be certain the email address listed in your professional profile is active, since it will be used to notify you throughout the review and award process.

Preliminary Notification and Likelihood of Funding. Following review of an application, preliminary information regarding its status will be emailed, with links to copies of the reviewers' critiques. This notification will also indicate the likelihood of funding, described by one of the following phrases:

- Your application has been recommended for funding.
- We cannot predict the likelihood of funding at this time.
- Your application is not likely to be funded.

All final funding decisions are made by the Council for Extramural Research, which typically meets in March and September.

The Scientific Director and Program Coordinator will shepherd your application through the entire process. Applicants may call the Extramural Research Department at any time during the cycle; after carefully considering the critiques, applicants are encouraged to contact their Scientific Director to discuss their review. Applicants considering resubmission are strongly encouraged to reach out in advance of the next deadline.

11. GRANT MANAGEMENT AND PAYMENTS

New grantees will receive a packet of information with instructions for activating the award. The activation form as well as other important information about the grant can also be found at <https://proposalcentral.altum.com>. (Select the Award tab to see the Post Award Management site.)

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 makes all payments to the sponsoring institution and mails them to the address shown on the grant activation form.

Acknowledgement of payment by the sponsoring institution is not required. Continued funding by ACS throughout the grant period is contingent upon the institution's compliance with all terms related to the grant; failure to comply with all of the grant terms may result in a suspension or cancellation of the grant, to be determined by ACS at its sole discretion.

Personnel compensated in whole or in part with funds from the American Cancer Society are not employees of the Society. Consequently, institutions are responsible for issuing appropriate IRS tax filings for all individuals receiving compensation from ACS grants, and for withholding and paying all required federal, state, and local payroll taxes for such compensation. Any 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.

12. ANNUAL AND FINAL PROGRESS REPORTS

The following policies apply to Research Scholar Grants, Mentored Research Scholar Grants, Clinician Scientist Development Grant, and Postdoctoral Fellowships. For all other grants, see the appropriate sections on Required Progress Reports. Annual and final reports represent a

critical part of responsible stewardship of the donated dollars, and we greatly appreciate your assistance in fulfilling this important commitment to our donors and yours.

- A. Both nontechnical and scientific progress reports are to be submitted each year within 60 days after the first and subsequent anniversaries of the start date of the grant. Final reports are due within 60 days after the grant has terminated. Forms for these reports can be found at <https://proposalcentral.altum.com>.
- 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 60 days after the official termination date of the grant. If the grant is terminated early, a final report must still be completed within 60 days of the termination date.
- C. Grantees must submit reports in a timely manner. If this is not possible, a grantee must make a written request to extend the reporting deadline. Noncompliance may result in the withholding of payment on all grants in effect at the recipient institution until reports are received.
- D. Please note that up-to-date annual reports are required when requesting any grant modifications, including transfers or no-cost extensions.

13. PUBLICATIONS AND OTHER GRANT-RELATED COMMUNICATIONS

When and how to acknowledge your ACS grant:

Publications resulting from research or training activities supported by the American Cancer Society must contain the following acknowledgment: “Supported by [name of grant and number] from the American Cancer Society.” When there are multiple sources of support, the acknowledgment should read “Supported in part by [name of grant and number] from the American Cancer Society,” along with references to other funding sources.

The Society’s support should also be acknowledged by the grantee and 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 ACS approval process for publications by Society grantees, it is helpful to notify your Scientific Director when manuscripts have been accepted for publication. This will allow ample time to for additional public or Society-wide notifications. If your institution plans a press release involving any of your Society-supported research, please notify the ACS communications representative (phone number on your award letter) or your Scientific Director in advance.

ACS grants to you a limited, revocable, non-transferable license to use the ACS logo (as shown below) in association with your funded work. We encourage you to use it on scientific posters, Power Point presentations, and any other visual presentation about your funded work where the

ACS is noted as a funding source. In turn, you agree to provide any materials featuring the ACS logo upon our request.

Permission to use the logo is limited to the uses outlined in the above paragraph. It should not imply ACS endorsement of products such as guidelines, websites, software for mobile devices (apps), tool kits, and so on.



14. FINANCIAL RECORDS AND REPORTS

A report of expenditures must be submitted within 90 days of the grant's expiration date shown in the award letter; annual financial reports are not required. Any change in terms, such as a no-cost extension, will alter a report's due date. The necessary forms can be found at <https://proposalcentral.altum.com>.

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

Grantees must submit financial reports in a timely manner. If this is not possible, a grantee must make a written request to extend the reporting deadline. Noncompliance 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, 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 19, "Cancellation.")

Note: The Institutional Research Grant has different reporting requirements, found in the Required Financial Reports section in the IRG policies.

15. EXPENDITURES

American Cancer Society *research* grants are not designed to cover the total cost of the research proposed or the investigator's entire compensation. The grantee's institution is expected to provide the required physical facilities and administrative services normally available at an institution.

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

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

- **Travel**
 - Foreign travel (special consideration is given for attendance at scientific meetings held in Canada).
- **Administrative**
 - Secretarial or administrative salaries.
 - Membership dues.
- **Tuition, books, and fees**
 - Student tuition and fees (graduate or undergraduate). However, tuition is an allowable expense for the principal investigator of a Clinician Scientist Development Grant.
 - Books and periodicals, except required texts for coursework in the approved training plan for Clinician Scientist Development Grants.
- **Office or laboratory setup and expenses**
 - Office and laboratory furniture.
 - Office equipment and supplies.
 - Rental of office or laboratory space.
 - Construction, renovation, or maintenance of buildings or laboratories.
- **Other**
 - Recruiting and relocation expenses.
 - Non-medical services to patients (travel to a clinical site or patient incentives are allowable expenses).

Society research and training grant funds can be used for computers for research and training purposes, which can be purchased with direct funds from the equipment budget. See specific policies for different funding mechanisms.

16. OWNERSHIP OF EQUIPMENT

Equipment purchased under American Cancer Society research grants or grant extensions 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, and title to such equipment shall be vested in the new institution.

17. 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"), excluding postdoctoral fellowship Grantees at the National Institutes of Health and other government laboratories, for whom the applicable patent policies of the federal government shall apply. 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 the 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, at the Society's expense, for any Funded Invention in any country where Grantee has decided not to seek 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.

Please note that the American Cancer Society is unable to renegotiate the terms of this agreement with any individual institution.

18. REQUEST FOR GRANT MODIFICATIONS

- **Extension**

A request for the extension of a grant term without additional funds must be submitted in writing to the Scientific Director 90 days before the grant's expiration date; a form can be found at <https://proposalcentral.com>. Include an estimate of the funds to be carried over into the extension, and an explanation for the delay—i.e. which specific aims remain incomplete and why. In general, a grant may be extended for up to one year if a programmatic need is justified and the funds to be carried over into the no-cost period do not exceed an amount equivalent to one year of support (direct plus indirect costs).

- **Leave of absence**

Requests for a leave of absence will be handled on a case-by-case basis. Please contact the Scientific Director at least 30 days prior to the proposed beginning of leave. An appropriate form can be found at <https://proposalcentral.com>.

- **Request to transfer institution**

A grantee who plans to change institutions during the grant period must contact the Scientific Director to initiate the transfer request process. An appropriate form can be found at <https://proposalcentral.com>.

Please note that up-to-date annual reports are required prior to approval of any grant modifications including transfers and no-cost extensions.

The Society reserves the right to deny requests for extensions, leaves of absence, or transfers.

19. CANCELLATION OF GRANT

If a grant is to be canceled prior to the original termination date, contact your Scientific Director and submit the Request for Cancellation form found at <https://proposalcentral.com>. The American Cancer Society may cancel a grant at its sole discretion if the institution fails to comply with all of the terms and obligations related to the grant.

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. If a Postdoctoral Fellowship is cancelled prior to its end date, payments of the fellowship allowance will be prorated on a monthly basis. Please see the specific policies for Institutional Research Grants regarding the cancellation of a pilot project grant. The Society assumes no responsibility for expenditures in excess of the prorated amount.

For 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. Please see the specific policies for Master's Training Grants in Clinical Oncology Social Work and Physician Training Awards in Cancer Prevention for instructions regarding a student or resident who does not complete training.

If an award is canceled after the initiation of the grant period, a final report will be due within 60 days of the termination date describing the work completed up to that point.

20. OVERVIEW OF PILOT AND EXPLORATORY PROJECTS

The Pilot and Exploratory Project mechanism is intended to provide support for a small pilot or exploratory project whose purpose is to test interventions, develop research methodologies and explore novel areas as defined in the RFA. This mechanism currently supports the following RFA:

Pilot and Exploratory Projects in Palliative Care of Cancer Patients and Their Families

Palliative care is medical care that specializes in the relief of pain and other symptoms related to cancer and its treatment. Palliative care research focuses on the prevention and relief of suffering by the early identification, assessment and treatment of pain, as well as of other physical, psychosocial and spiritual problems associated with cancer. Reducing suffering and improving the quality of care

and quality of life for patients, family members and caregivers is a major goal for this area of care. This is limited to research in human subjects and may focus on decision making, treatment, symptom control, team care, engaging family members and caregivers to address communication barriers and/or optimal symptom management. The Society partnered closely with the National Palliative Care Research Center (NPCRC) to formulate this mechanism and the NPCRC has continued to be a valuable partner. (<http://www.npcrc.org/>)

Recommended Palliative Care Resources:

- “From Cancer Patient to Cancer Survivor: Lost in Translation,” Institute of Medicine.
- American Academy of Pain Management, Index of Resources.
- National Cancer Survivorship Resource Center.
<http://www.cancer.org/treatment/survivorshipduringandaftertreatment/nationalcancersurvivorshipresourcecenter/index>
- National Hospice and Palliative Care Organization, Index of Resources.
<http://www.nhpc.org/resources>

21. ELIGIBILITY FOR PILOT AND EXPLORATORY PROJECTS

1. Applicants must hold a doctorate degree (M.D., Ph.D., or equivalent) and have a full-time faculty position or equivalent at a college, university, medical school, or other fiscally responsible not-for-profit organization within the United States.
2. Independent investigators at **all** stages of their career are eligible to apply. Thus, the usual ACS restriction to investigators within the first six years of their initial independent research appointment does **not** apply to this RFA.

22. TERMS OF AWARD OF PILOT AND EXPLORATORY PROJECTS

A. Budget and Term of Award

Awards may not exceed a period of two years duration with a maximum budget of \$60,000 per year plus 20% indirect costs. Salary support for the Principal Investigator may not exceed 20% of the funded project’s direct costs.

B. Resubmission of Unfunded Applications

- Applications that are not funded may be revised and resubmitted two additional times (i.e., a total of 3 times).
- Applications for RFAs may only be submitted during cycles when the RFA is active. (RFA is active when it is posted online.)

C. Renewals and Extensions of Awarded Grants

- These grants are not renewable.
- The termination date of any grant may be extended for up to one year without additional funds upon written request from the Principal Investigator. The Program Director must receive this request 30 days before the expiration date of the grant.

23. EVALUATION OF APPLICATIONS

The committees will evaluate applications on all of the following criteria:

- **Significance**

Does the project address an important problem or a critical barrier to progress in the field? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice improve? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field? If aims are realized how will the results of this study impact cancer health equity, cancer disparities, social change, and/or policy?

- **Cancer Relevance**

How is this research relevant to persons at risk for, or living with, cancer and their family members, caregivers and friends and community?

- **Innovation**

Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

- **Investigators**

Does the PI and research team have the training and experience needed to carry out the proposed research? Do team members have the complementary skills and qualifications needed for successful implementation and analysis of the proposed research? Has the research team previously collaborated on research or publications? If not, are members of the proposed study team appropriate to carry out the research?

- **Approach**

Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project. How will the successful completion of the work proposed in the specific aims advance scientific knowledge of palliative care in one or more of the following areas for patients, their families and /or caregivers:

Quality of Life- improving and managing pain or other distressing symptoms; improving physical functioning, or providing emotional or spiritual support

Effective communication-informed and shared decision-making with cancer survivors, their families; improving healthcare team's communication effectiveness

Quality of care: testing novel models of delivering high quality palliative care or system level intervention to improve access to care, care coordination or outcomes for cancer patients and their families.

Are potential problems, alternative strategies, and benchmarks for success presented with relevance to the community? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed? Are plans for data collection and analysis well-reasoned? Do investigators include relevant and limitations? Is the sample size sufficient to conduct sub-analysis if the targeted

populations(s)? If a program project, are evaluation plans and logic model included? Are study timelines feasible to carry-out the scope of work and future a meaningful and logical extension of the proposal under review?

- **Environment**

Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

- **Potential for Future Funding of Project** – A clearly defined plan as to how the investigator will use the results of the project to develop larger, extramurally funded research projects is an integral part of this mechanism. Is there a clearly defined plan of how the data and/or process information generated will be used to develop a larger, extramurally funded project?

APPENDIX A: GUIDELINES FOR MAINTAINING RESEARCH AND PEER REVIEW INTEGRITY

The American Cancer Society seeks excellence in the discovery and dissemination of knowledge regarding the cause, prevention, detection and diagnosis, treatment, survivorship and health policy of cancer. This requires that all individuals affiliated with, or funded by, the American Cancer Society adhere to the highest standards of professional integrity. Volunteer grant reviewers for the American Cancer Society will also be held to the highest codes of conduct and integrity in performing their essential function of peer review.

The American Cancer Society provides grant funds for individuals at academic and other not-for-profit institutions to promote cancer-related training, research and treatment. This represents a contractual relationship with such institutions, and it is an accepted responsibility and obligation of those institutions to provide policies and procedures for their faculty, staff and students that address possible misconduct in training, research and treatment of patients. Moreover, it is the responsibility and obligation of faculty, students and staff engaged in scientific research and training to be aware of policies and procedures for addressing possible misconduct at their institutions, and to follow those procedures in reporting possible misconduct.

While questions of the integrity of applicants, grantees, and reviewers are very infrequent, they do occur. It is the responsibility of the Program Directors managing the review process and portfolios of funded grants and the responsibility of the Senior Vice President for Extramural Research to ensure that all questions regarding research integrity are handled in a discrete, but thorough manner. The actions of the Program Directors and the Senior Vice President for Extramural Research must ensure the confidentiality and anonymity of the individual raising the question of misconduct; ensure the integrity of the American Cancer Society and its review processes; ensure the rights of the individual accused of misconduct; and ensure their own credibility and integrity.

Article I

Standards and Definitions:

1.1 Research Misconduct by Applicants or Grantees

The American Cancer Society uses the following definitions related to scientific misconduct outlined in the Federal Guidelines [Federal Register, Vol. 65, No. 235, pg. 76260-76264].

- Research misconduct is defined as fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.¹
- Research, as used herein, includes all basic, applied, and demonstration research in all fields of science, engineering, and mathematics. This includes, but is not limited to, research in economics, education, linguistics, medicine, biology, chemistry, psychology, natural sciences, social sciences, statistics, and research involving human subjects or animals.¹

- Fabrication is defined as making up data or results and recording or reporting them.¹
- Falsification is defined as manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.¹
- The research record is defined as the record of data or results that embody the facts resulting from scientific inquiry, and includes, but is not limited to, research proposals, laboratory records, both physical and electronic, progress reports, abstracts, theses, oral presentations, internal reports, and journal articles.¹
- Plagiarism is defined as the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.
- Research misconduct does not include honest error or differences of opinion.¹
- Reported Qualifications must be accurate (e.g. years since degree earned).

1.2 Research Misconduct by Peer Review Committee Members

The American Cancer Society has adopted the following definitions of misconduct in review by members of a Peer Review Committee. Misconduct in review is defined as:

- Review for an application for which there is a clear conflict of interest between the reviewer and applicant.
- Failure to notify ACS personnel of actual, potential, perceived or potentially perceived conflicts of interest.
- Any communication pertaining to review related materials between a member[s] of a peer review committee and an applicant, or the mentor of an applicant, in the case of applications with an element of training as part of the application.
- Any communication of the unpublished content of a grant application by a member or members of a peer review committee with any individual who is not a permanent or ad hoc member of the peer review committee to which an application is assigned, or who has not been approved by the Program Director for such communication.
- Any use of the unpublished content or concepts of a grant application in pursuit of scientific or career goals by a member of a peer review committee.
- Any review of, or use of, the contents of a grant application by a member or members of a peer review committee who might have, or be perceived to have, a conflict of interest with the applicant or his/her mentor, in the case of applications with an element of training as part of the application

1.3 Confidentiality Standard for Reviewers

To preserve the integrity of the peer review process, all parties involved in the review process must adhere to the following practices regarding confidentiality and non-disclosure:

- Reviewers must not discuss applications reviewed with any individual not designated as a part of the review process; and especially not with applicants, or

¹ The above definitions are outlined in the Federal Guidelines [Federal Register, Vol.65, No.235, pg.: 76260-76264]

their mentors in the case of training grants, either before or after the peer review meetings.

- Any inquiries to a peer review panel member regarding an application from an applicant, PI, Co-PIs, consultants or their mentor, to a member of a Peer Review Committee or ACS Council for Extramural Grants must be reported immediately to the Program Director.
- All materials related to the review process must be destroyed or given to the Program Coordinator at the end of the review meeting.
- For purposes of this standard, materials related to the review process include, but are not limited to: paper, bound volumes, compact disks (CDs), flash drives, electronic files accessed via the internet, or oral presentations or discussions.

1.4 Conflict of Interest Standard for Reviewers

To preserve the integrity of the peer review process, all participants in the process must adhere to these principles and practices:

- Reviewers must not be an employer or employee of an applicant, and may not be employed by the same institution as an applicant within three years of the date of submission of an application
- Reviewers must not be a party to any agreement for future employment or other agreements or arrangements with an applicant or any person listed as key personnel on an application
- Reviewers must not have served as mentors or collaborators of an applicant within 3 years of the date of an application
- Reviewers must not participate in the review of an application submitted by a standing member of a Peer Review Committee serving on the same review committee, with the exception of Health Professional Training Grants or Institutional Research Grants
- Reviewers must not be under the health care of, or providing health care to, an applicant or any person listed as key personnel on an application
- Reviewers must not have received or have the potential to receive direct financial benefit from the application
- Reviewers must not be pursuing research projects which might be viewed as being in direct competition with applicants or their collaborators and colleagues; nor have potential to receive direct benefit from failure of the application to be funded
- Reviewers must not have any cause of action against, any dispute with, any long-standing scientific or personal differences with, or any claim whatsoever against the applicant or any person listed as key personnel on an application

Articles II

Policies:

2.1 Policy Governing Misconduct by Applicants and Grantees

2.1.1 Applicants:

Any allegations of scientific misconduct must be brought to the immediate attention of the Program Director in charge of the Peer Review Committee which is responsible for reviewing the work in question. If possible, allegations of misconduct on the part of an applicant in the submission of a grant proposal should be raised in advance of the review meeting. The Program Director will then bring the allegation to the attention of the Senior Vice President for Extramural Research at ACS. The Senior Vice President for Extramural Research will evaluate the allegation and make a determination on the misconduct issue and the appropriate next steps to be taken to engage in further investigation or action in accordance with Article III “Procedures for Handling Conflicts of Interest and Allegations or Findings of Misconduct in Research and Peer Review”.

2.1.2 Grantees:

In instances where alleged scientific misconduct occurs after the awarding of a grant, such as in the publication of falsified data, the Program Director will bring the allegation to the attention of the Senior Vice President for Extramural Research at ACS. The Senior Vice President for Extramural Research will evaluate the allegation and make a determination of the appropriate steps to be taken to engage in further investigation or action as defined in Article III, “Procedures for Handling Conflicts of Interest and Allegations or Findings of Misconduct in Research and Peer Review”.

2.2 Policy Governing Misconduct by Peer Review Committee Members

2.2.1 Confidentiality:

Confidentiality is at the heart of the peer review process and is imperative for objective evaluation and free expression in the review process. The applicant-reviewer relationship is a privileged alliance founded on the ethical rule of confidentiality.² To maintain the essence and integrity of the peer review process, the Society and its appointed peer reviewers must ensure and be assured that the confidentiality of the applicant’s information, the contents of the grant application, and of the proceedings of the review panel will be maintained. Such confidentiality adheres when a person discloses information to another with the understanding that the information will not be divulged to others without the discloser’s consent, or as otherwise required by law. In the context of peer review, this rule upholds the applicants’ rights to have the information they submit, whether in proposal form or in communications, kept confidential. The rule also ensures that those involved in the review process maintain their obligation to keep confidential any information concerning an application. In fact, the very existence of a submission should not be revealed (or confirmed) to anyone other than those within the review process unless and until the application is funded.

To this end, all contents, evaluation and discussion of applications shall be confined to Peer Review Committee (PRC) members and ACS staff personnel (Program Director, Senior Vice President for Extramural Research, Program Coordinator, support staff) responsible for managing the review process of that PRC. For these purposes, reviewers include all standing and ad hoc reviewers of PRCs and members of the Council for Extramural Grants. In rare and specific instances, discussion of applications with, or in the presence of, non-committee members can occur

after obtaining the written consent of the Program Director. Reviewers must not discuss reviews with applicants or their mentors in the case of training grants, either before or after the review meetings. Reviewers also must not communicate the contents of any grant applications with individuals not associated with the review process. Any materials related to the review process must be disposed of at the meeting, and all final critiques given to the Program Director for inclusion in summary statements.

If an allegation of a breach of reviewer confidentiality is brought forward, that allegation will be communicated to the Senior Vice President for Extramural Research who will determine if an investigation of that allegation is warranted. The Senior Vice President for Extramural Research will then follow the appropriate steps as defined in Article III, “Procedures for Handling Conflicts of Interest and Allegations or Findings of Misconduct in Research and Peer Review”.

2.2.2 Conflict of Interest:

An objective evaluation of grant proposals is essential to the peer review process. In achieving this goal, there must be no conflict of interest, apparent conflict of interest or pending future conflict of interest between any participant in the review process and the applicants or their collaborators and colleagues. In this setting, reviewers include standing and ad hoc Peer Review Committee (PRC) members and members of the ACS Council for Extramural Grants responsible for, and participating in, the review process. There are numerous bases for conflicts of interest, and these can include: employment, professional relationships, personal relationships, financial benefit, industry affiliation or other interests. The conflicts can be real or apparent. For Definitions of Conflict of Interest, refer to Section 1.4.

Reviewers may not make use of any of the contents of a grant for their own research purposes or those of their collaborators and colleagues. Reviewers must exercise proper due diligence in investigating and disclosing any potential conflict of interest that might exist between themselves and an applicant or the applicant’s collaborators or mentors. The Conflict of Interest Statement attached as EXHIBIT A shall be submitted to the Senior Vice President for Extramural Research for review at least sixty (60) days prior to the beginning of the Peer Review cycle.

If an allegation of a reviewer conflict of interest is brought forward, that allegation will be communicated to the Senior Vice President for Extramural Research who will determine if an investigation of that allegation is warranted. The Senior Vice President for Extramural Research will then follow the appropriate steps as defined in Article III “Procedures for Handling Conflicts of Interest and Allegations or Findings of Misconduct”.

Article III

Procedures for Handling Conflicts of Interest and Allegations or Findings of Misconduct:

To ensure the integrity of the peer review process and the integrity of ACS-sponsored research, it is necessary that the procedures for dealing with allegations of misconduct be clearly understood by all reviewers and ACS personnel. Procedures for handling allegations of misconduct by applicants, grantees and reviewers are detailed in the following sections.

3.1 Procedures for Handling an Allegation of Scientific Misconduct by Applicants or Grantees

3.1.1 Misconduct by Applicants:

In the event that an allegation of scientific misconduct by an applicant is brought forward to a Program Director or other ACS staff, all effort must be made to investigate the validity of the allegation while maintaining the confidentiality of the individual making the allegation, the anonymity of the person against whom the allegation is made, and the integrity of the review process. The Program Director must immediately inform the Senior Vice President for Extramural Research of the allegation, and provide all relevant information regarding the allegation. It is the Senior Vice President's responsibility to evaluate the likelihood of scientific misconduct; and, if warranted, it is the Senior Vice President's responsibility to contact the appropriate institutional office at the applicant's institution regarding the allegation. The Senior Vice President for Extramural Research will then serve as the point of contact between the ACS and the institutional official[s] handling issues of scientific misconduct.

If determined to be appropriate, the Senior Vice President for Extramural Research will forward an allegation of misconduct and all pertinent information to the Research Integrity Officer at the institution sponsoring the grant application in question or at which the alleged misconduct was carried out. If there is not a Research Integrity Officer, the Dean of the School in question or its chief academic officer will be contacted. In the instance that the person[s] making the allegation does not contact the American Cancer Society but raises the allegation of misconduct with the appropriate institutional official according to their established institutional procedures, it is the responsibility of the institution to contact the American Cancer Society regarding the allegation, any investigation of the allegation, and the outcome of that investigation. All such correspondence will be held in strict confidence, and will not be made public by the American Cancer Society irrespective of the outcome of the investigation. The American Cancer Society assumes no responsibility in carrying out the investigation of scientific misconduct, or in determining an individual's innocence or guilt of the allegation of misconduct. However, acceptance or non-acceptance of the findings of the institutional investigation is at the discretion of the Senior Vice President, and additional clarification may be requested.

Allegations of scientific misconduct in a grant application may be made by individuals who are colleagues, trainees, or reviewers. In the instance that an allegation of misconduct is made in reference to a grant application, the Senior Vice President for Extramural Research will contact the institutional official at the sponsoring research institution and seek to follow their established protocol for investigating such allegations. If an investigation is deemed necessary, it will be the responsibility of the sponsoring institution to carry out the investigation, to keep the ACS aware of the progress, and to report the outcome of the investigation to the Senior Vice President for Extramural Research.

In fairness to the applicant, the review process must continue while the allegation of misconduct undergoes assessment. Review may continue either in the standing review committee or under the By-pass to Council review mechanism. *Under no circumstance* should a reviewer, Program Director or ACS staff raise the issue of the allegation in a peer review meeting or meeting

of ACS Council for Extramural Grants. If that were to occur, review of that application could not be completed without bias; and review of the application must therefore be deferred to ad hoc reviewers or the ACS Council for Extramural Grants. If a reviewer suspects misconduct, which is discovered at the time of the meeting, it is appropriate to request the Chair of the PRC or Council take a "break" and discuss the issue privately with the Program Director. The Program Director will then take the proscribed administrative steps following the adjournment of the review meeting.

The ACS will complete the process of peer review of the application, but will suspend any administrative action which would result in funding of the award in question until the resolution of the investigation. At the conclusion of the investigation, the ACS will require the Office of Research Integrity or comparable entity at the applicant's sponsoring institution to provide a written statement detailing the results of the investigation. Failure of the institution to carry out such an investigation in a timely manner or to provide written results of the investigation will result in the administrative disapproval of the application. If the applicant is absolved of any scientific misconduct, the ACS will reinstitute administrative action that can result in funding for the award if it was approved and is within the pay-line established by ACS Council for Extramural Grants. In the instance that misconduct has occurred, the ACS will administratively inactive the application. Also, in the case of a finding of scientific misconduct, the investigator may no longer be eligible to participate in ACS funded awards, either as principal investigator, co-investigator, collaborator, mentor or consultant. The investigator also may not be eligible to serve in any capacity in reviewing ACS grant proposals.

3.1.2 Misconduct by Grantees:

In the event that an allegation of scientific misconduct by a grantee is brought forward to a Program Director or other ACS staff, all effort must be made to investigate the validity of the allegation while maintaining the confidentiality of the individual making the allegation and the anonymity of the person against whom the allegation is made. The Program Director or ACS staff contacted about the alleged misconduct must immediately inform the Senior Vice President for Extramural Research of the allegation, and provide all relevant information regarding the allegation. It is the Senior Vice President's responsibility to evaluate the likelihood of scientific misconduct; and, if warranted, it is the Senior Vice President for Extramural Research's responsibility to contact the appropriate institutional office at the applicant's institution regarding the allegation. The Senior Vice President for Extramural Research will then serve as the point of contact between the ACS and the institutional official[s] handling issues of scientific misconduct.

If determined to be appropriate, the Senior Vice President for Extramural Research will forward an allegation of misconduct and all pertinent information to the Research Integrity Officer at the institution sponsoring the grant in question or at which the alleged misconduct was carried out. If there is not a Research Integrity Officer, the Dean of the School in question or its chief academic officer will be contacted. In the instance that the person[s] making the allegation does not contact the American Cancer Society but raises the allegation of misconduct with the appropriate institutional official according to their established institutional procedures, it is the responsibility of the institution to contact the American Cancer Society regarding the allegation, any investigation of the allegation, and the outcome of that investigation. All such correspondence will be held in strict confidence, and will not be made public by the American Cancer Society

irrespective of the outcome of the investigation. The American Cancer Society assumes no responsibility in carrying out the investigation of scientific misconduct, or in determining an individual's innocence or guilt of the allegation of misconduct. However, failure of the institution to immediately notify ACS of an allegation and/or investigation of misconduct, or to carry out a misconduct investigation in a timely manner, or to provide written results of the investigation, is in non-conformance with the terms and obligations of the grant and may result in the suspension of ACS funds for all grants awarded at the institution, to be decided by ACS in its sole discretion. The American Cancer Society assumes no responsibility in carrying out the investigation of scientific misconduct, or in determining an individual's innocence or guilt of the allegation of misconduct. However, acceptance or non-acceptance of the findings of the institutional investigation is at the discretion of the Senior Vice President, and additional clarification may be requested.

If the investigator has an active ACS award, funding of that award will be suspended until the allegation has either been confirmed or be proven to be erroneous. If the allegation is proven not to have merit, the award may be reinstated by ACS at the date of notification of those findings by the sponsoring institution. If the allegation of misconduct is confirmed, the award will be terminated and any residual funds, as of the date of notification of the sponsoring institution of the allegation, must be returned to the ACS. In the case of a finding of scientific misconduct, the investigator may no longer be eligible to participate in ACS funded awards, either as principal investigator, co-investigator, collaborator, mentor, or consultant. The investigator may also not be eligible to serve in any capacity in reviewing ACS grant proposals.

The publication of data serves to further the interests of the scientific pursuit, and specifically in the case of the ACS, the pursuit of eliminating the burden of cancer. Therefore, it is incumbent on both the ACS and the scientific community to insure that any instances of misrepresentation of findings in a scientific study are apparent to the scientific community. To that end, a finding of falsification or misrepresentation of data in a published forum must be reported to the editor-in-chief of the journal in which such data is reported. It is the responsibility of the Senior Vice President for Extramural Research to coordinate such notification with the appropriate sponsoring institutional official according to their established policies and in conjunction with the policies of the journal. If the sponsoring institution does not have a policy regarding notification of the journal, then the Senior Vice President for Extramural Research will notify the editor-in-chief of the journal according to the journal's established policies.

In the case of findings of falsification or misrepresentation of published data supported by ACS funds, any active grant[s] held by the responsible individual will be terminated and that individual may no longer be eligible for ACS funding via any mechanism as a principal investigator, co-investigator, collaborator, mentor, or consultant. That individual may also not be eligible to participate in ACS review in any capacity.

3.1.3 Reviewer Misconduct and Conflict of Interest

In the event that an allegation of reviewer misconduct, such as failure to acknowledge a conflict of interest, is brought forward to a Program Director or other ACS staff, all effort must be made to investigate the validity of the allegation while maintaining the confidentiality of the

individual making the allegation, the anonymity of the person against whom the allegation is made, and the integrity of the review process. The Program Director or other ACS staff contacted regarding the alleged misconduct must immediately inform the Senior Vice President for Extramural Research of the allegation, and provide all relevant information regarding the allegation. It is the Senior Vice President for Extramural Research's responsibility to evaluate the likelihood of reviewer conflict of interest or misconduct; and, if warranted, it is the Senior Vice President for Extramural Research's responsibility to handle the investigation internally or to inform the appropriate institutional office at the reviewer's institution about the allegation if aspects of the reviewer misconduct violate any of the tenets of professional behavior established by that institution. The Senior Vice President for Extramural Research will then serve as the point of contact between the ACS and the institutional official handling issues of reviewer misconduct.

Some elements of reviewer misconduct represent conduct that will only have relevance for the appropriateness of the reviewer's role as a member of a peer review committee. For instance, if there is inappropriate communication between reviewer and applicant or an applicant's mentor or colleagues. In a case of this type, all elements of the investigation of the reviewer misconduct will be handled by ACS personnel at the discretion of the Senior Vice President for Extramural Research. In cases where a reviewer does not retain the confidentiality of the applicant's information or the content of his or her application, and makes that information available to a third party, it will be at the discretion of the Senior Vice President for Extramural Research to handle the issue internally at ACS or contact the Office of Research Integrity at the reviewer's institution, based upon an initial assessment of whether such conduct violates the rules of conduct established by that institution. For instance, if there is communication of the contents of a grant proposal by a reviewer to a competitor in the same field as the applicant, or if the reviewer makes use of findings or ideas in an application to further his or her own research interests. In the instance of such an allegation, the American Cancer Society assumes no responsibility for carrying out the investigation of scientific misconduct, or in determining an individual's innocence or guilt of the allegation of misconduct. It is the institution's responsibility to handle the misconduct according to their established procedures. However, acceptance or non-acceptance of the findings of the institutional investigation is at the discretion of the Senior Vice President, and additional clarification may be requested. In any instance of a finding of reviewer misconduct, that individual may no longer be eligible to serve in any capacity in reviewing ACS grant proposals, and may be barred from receiving any ACS grant funds.

²This section is adapted from "Confidentiality in Peer Review" (section 3.7.1). Pugh MB, ed. American Medical Association Manual of Style: a guide for authors and editors. 9th ed. Baltimore, MD: Williams & Wilkins; 1997:136-137; and from the American Cancer Society Confidentiality, Non Disclosure Rules and Conflict of Interest: Information for Reviewers of Grant Applications, Version 6/3/2005

APPENDIX B: 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 INVESTIGATOR REPORTS OF EXPENDITURES

The American Cancer Society subscribes to the Altum proposalCENTRAL **Post Award Management System** to facilitate management ACS grants. The system is designed to collect and store grant information from grantees. Grantees are asked to keep their proposalCENTRAL profile current for the duration of the grant.

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 **only**, please also email April Jones at april.jones@cancer.org in the Research Business office notifying her that you have uploaded your Grant Activation Form.

Uploading an Award Deliverable

- Log onto <https://proposalcentral.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.

- 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.com/>
- 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: pcsupport@altum.com

PILOT AND EXPLORATORY PROJECT

INSTRUCTIONS

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A. GENERAL INFORMATION

1. AMERICAN CANCER SOCIETY (ACS) GRANT APPLICATION SYSTEM

- Access the ACS Research site at www.cancer.org.
- Select “Our Research” > “Apply for Grant” > “Grant Types”.
- Select link to your grant, which opens the electronic application process at proposalCENTRAL.
- Follow instructions for login/register, completion, and submission.
- Key steps:
 - “Create New Proposal” > “Grant Types” > “Apply Now”
 - Enter Project Title (unless already displayed) > SAVE. This permits access to other application components.
 - Saved applications are stored under the “Manage Proposals”.
- See proposalCENTRAL login page for tutorials and additional details about the grant application process.
- Alternatively, click “Help” or contact ALTUM Customer Service at pcsupport@altum.com or 1-800-875-2562.

2. FORMAT

- Insert Principal Investigator (PI) name in the header for each template of the application. Do not change the footers on the templates.
- Application documents may be single- or double-sided (if single spacing, enter a space between paragraphs).
- **Type size:** 12-point Times New Roman or 11-point Arial are the minimum font sizes for the text; 10-point Times New Roman or 9-point Arial font type may be used for figures, legends, and tables.
- **Margins:** \geq 0.5 inches all around, unless a form with different margins is supplied in the Application Templates.
- **Page numbering:**
 - Number in upper right corner:* Proposal Sections. They will be listed in the Table of Contents.
 - Do not number:* Cover pages (Signature Page, Contact Page, General Audience Summary, Structured Technical Abstract, and Proposed Budget, if applicable) and Appendix.

3. UPDATES OF INFORMATION

The following updates should be communicated as specified to your Scientific Director. If it is before you have received an application number, contact the Extramural Research Department at grants@cancer.org.

Withdrawal of Application: Notify the Department promptly of your intent to withdraw your application. Include in your letter or email, the PI name, application number, and reason for withdrawal. If the project has been funded by another organization, please list that funding agency.

Change of Address: Notify the Department via email if a mailing address, email address, or phone number has changed since a submission. Include the PI name and application number on the correspondence and update your information in proposalCENTRAL.

Change of Institution: If you change institutions between application submission and peer review, contact the Scientific Director to inquire how this may impact the review.

4. REQUIRED INFORMATION

Note: Not all fields are required for all applications; see grant-specific instructions.

Project Title: Do not exceed 75 characters including spaces; avoid abbreviations if possible.

Principal Investigator/Applicant Information: Some (or all) of the required information from your Professional Profile may already display from your profile. If any information is outdated, *stop* and update the Professional Profile before completing this section and submitting an application. Please keep all contact information current.

Key Personnel: Individuals who contribute to the scientific development or execution of a project in a substantive and measurable way (whether or not they receive salaries or compensation under the grant) are considered Key Personnel. **The PI is always considered Key Personnel, but do not list them under key personnel on proposalCENTRAL.**

Key Personnel can include individuals at the master's or baccalaureate level (such as graduate students and research assistants) if they meet this definition. "Zero percent" or "as needed" are not acceptable levels of involvement.

The **Principal Investigator** assumes the authority and responsibility to direct the project. The ACS does not permit applications to be directed by Co-Principal Investigators.

A **Co-Investigator** is a vital scientific contributor (at the same or a different institution), often bringing a needed expertise to the research team. This person commits some level of measurable effort to the project and is therefore Key Personnel, whether compensated or not.

A **Collaborator** plays a lesser role in the thinking and logistics of the project than a Co-Investigator. Depending on the role and effort, a collaborator may be designated as Key Personnel and may be compensated.

A **Consultant** provides expert advice, most often for a fee. Generally, a consultant is not considered Key Personnel. However, if the consultant contributes to the scientific development or execution of a project substantively and measurably, he or she should be designated as such.

Other is defined as individuals who are compensated for their contribution to the project but are not considered Key Personnel (e.g. student assistants, technical staff).

The table below provides information about the documents required for each personnel class. See grant-specific instructions for detailed guidance.

REQUIRED SUPPORTING DOCUMENTS FOR NAMED PERSONNEL

Personnel	Designated “Key”	Biosketch	“Other Support” Documentation	Included in Budget & Justification	Letters
Principal Investigator	Yes ^a	Yes	Yes	Yes	N/A
Co-Investigator	Yes	Yes	Yes ^b	Yes ^c	Letter of Agreement/Support ^b
Collaborator	Yes	Yes	Yes ^b	Yes ^c	Letter of Agreement/Support ^b
	No	No	No	No	
Consultant	Yes	Yes	Yes ^b	Yes ^c	Letter of Agreement/Support ^b
	No	No	No	No	
Other	No	No	No	Yes	No

^aThe PI is always considered key personnel but supporting documents should **not** be duplicated in the Key Personnel section on proposalCENTRAL.

^bFor postdoctoral fellows, technicians, and graduate students, other support documentation is not required.

^cIf key personnel are not being paid, include ‘in kind’ for dollar amount; percent effort is required.

Some mentored and health professional training grants, such as Doctoral Scholarships in Cancer Nursing, have other contributors (e.g., **Mentor** and **Preceptor**). *See grant-specific instructions for definitions and required supporting documents.*

Citizenship Status (mandatory): On proposalCENTRAL under “Professional Profile”, indicate your current citizenship status and country of citizenship.

Justification of Eligibility: Applicants must satisfy all eligibility requirements defined for each application type. On the cover page, indicate when (months and year) your terminal degree was awarded and your first independent faculty position (or equivalent), if applicable. If you have a letter from the ACS Eligibility Committee, include it in the Appendix and Table of Contents.

Justification of Designation “Priority Focus in Health Equity Research:” Indicate on the title page “Health Equity” if the proposal falls into the Priority Focus (Health Equity Research) in the Cancer Control and Prevention Research Program.

Space: If applicable, indicate the approximate area of independent research space provided by your institution to support your research program, along with the name of the department head who can verify this commitment. You must insert a value for square footage on the electronic form, even if that number is zero.

Institutional Official: Indicate the name and address of the official authorized to sign for the institution. Institutional officials must sign the front page; electronic signatures are acceptable. Provide a mailing address for disbursement of funds, in the event that your grant is awarded funding.

Department Chair: Indicate the name, department, and email address of the department head. The department head must sign the front page to affirm the title/position of the PI and the committed resources.

Primary Mentor: Complete all fields for mentor information (if applicable).

Additional Mentor(s): Complete all fields for additional mentor information (if applicable).

ORCID Identifier (optional): Please provide an ORCID identifier. To add the ORCID ID, click Professional Profile and connect/register for an ID. Once connected, return to your proposal and click Save.

5. GENERAL AUDIENCE SUMMARY

The general audience summary provides an overview of the proposed research for people who are *not* trained in the sciences. This summary may be read by peer review stakeholders, ACS staff members, potential donors, and the public.

- **Stakeholders** are individuals without formal scientific or medical training who are full voting members of peer review panels. The stakeholder uses the general summary to evaluate how the proposed work will benefit cancer patients and their families (i.e., the cancer relevancy).
- **ACS staff members** use these summaries to identify projects that align with the specific interests of **donors** and may share them with donors.
- Staff may use the summary for communicating to local media about ACS-funded studies. Summaries of all grants funded by the Society are also made available to the **public**. Therefore, do not include proprietary/confidential information.

The general audience summary should *not* duplicate the structured technical abstract but should be written in an understandable way for the general public. Describe concisely the background, significance, question(s) being asked, information to be obtained, and potential impact of your proposed research. If symbols or Greek characters must be used, they should be spelled out to avoid formatting problems. *See examples of General Audience Summaries in the Appendix.*

This form is limited to 3,000 characters including spaces and will truncate at that point. Comply with the character limit to permit readers (including peer reviewers) to fully appreciate the “big-picture perspective” of the proposal.

6. STRUCTURED TECHNICAL ABSTRACT

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 (see Appendix for an example).

Organize the abstract into the following sections:

- Background
- Objective/Hypothesis
- Specific Aims
- Study Design
- Cancer Relevance

This form is limited to 3,000 characters including spaces and will truncate at that point. Comply with the character limit to permit peer reviewers to fully appreciate the technical synopsis.

7. PROJECT CODING

Note: Project coding is not considered at peer review. Red asterisks indicate required fields; not all grant types require project coding.

Donors often have interests in funding specific types of cancer research. Your selection of project codes permits identification of proposals for consideration of donor-driven special funding. This information also assists the Society in communicating our research portfolio to the public.

Select the most appropriate Areas of Research (Common Scientific Outline—CSO) and Types of Cancer. Note that relevant items may be included under Resources and Infrastructure Related to [specific area]. See the Appendix for specific terms and examples.

8. ASSURANCES AND CERTIFICATION

All activities involving human subjects and vertebrate animals must be approved by the appropriate institutional committee before the application can be funded. Compliance with current US Department of Health and Human Services and ACS guidelines for conflict of interest, recombinant DNA, and scientific misconduct is also required. The signature of the institutional official verifies these approval and compliance requirements.

Vertebrate animals. Every proposal involving vertebrate animals must be approved by an 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 can be funded. Enter the date of the most recent IACUC approval in the space provided.

All research supported by the ACS (including subcontracted activities) involving vertebrate animals must be conducted at performance sites covered under an approved Animal Welfare Assurance. It is the responsibility of the institution to immediately report to the ACS any action, including recertification or loss of IACUC approval, that is pertinent to the work described in the grant application.

Human Subjects. All proposed research projects involving human subjects must be approved by an Institutional Review Board (IRB) at an institution approved by 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). Copies of the DHHS policy, assured status, and assurance numbers may be obtained from OHRP. Definitions and further clarification can be found at the [NIH Office of Extramural Research website](#).

If institutional review of human or vertebrate-animal subjects has not been finalized before the submission date of the application, you must indicate that approval is pending on the certification page and give the appropriate institutional reference numbers, if available. Certification of the completed review, clearly labeled with the assigned ACS application number, must be received prior to activation of a grant. Failure to comply may result in withholding of payments and/or cancellation of funding.

Note: Applications for the Institutional Research Grant (IRG) and some Health Professional Training Grants do not require submission of IRB and IACUC certifications. Regardless, institutions must comply with the requirements described above to use ACS grant funding for activities involving human subjects or vertebrate animals.

If a grant is funded, it is the responsibility of the institution to immediately report to the ACS any action, including recertification or loss of IRB approval, which occurs during the term of the award that is related to the work described in the grant application.

9. PI DATA

Submit this section electronically only. The requested PI information is for statistical purposes only and is not considered at peer review. This section will not print with the cover pages and should not be submitted with your paper copy.

10. RESUBMISSION

All resubmissions must create a new application on proposalCENTRAL. Applications that are not initially funded can generally be resubmitted twice (Postdoctoral Fellowship applications are an exception with only one resubmission). Applicants are strongly encouraged to contact the Scientific Director prior to resubmission to discuss the previous review.

Resubmission guidelines:

- Submit a complete application with a current date for both electronic and paper copies.
- The title of the project can be altered but **must** be 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.) from the previous application must be provided where requested on the title page.
- Place a “Reply to Previous Review,” not to exceed 3 pages, where indicated in the Table of Contents of the Application Templates section. It should clearly address all points raised in the previous review and direct the reader to the specific sections of the text where revisions

have been made. Edits in response to the reviewers' comments should be designated (e.g.: bold type, highlighting, line in the margin, underlining, etc.). Reviewers' previous critiques should be inserted immediately after the "Reply to Previous Review" as indicated in the Table of Contents.

11. APPLICATION SUBMISSION AND REQUIRED SIGNATURES

Applications must be submitted in two formats: an electronic version and a paper copy.

A. ELECTRONIC APPLICATION

- All application attachments, including the Appendix, must be uploaded as .pdf documents, *except for the signed copy of the front page*, which is to be submitted only with the paper copy. See proposalCENTRAL FAQ or contact support at 1-800-875-2562 for assistance.
- Validate the application on proposalCENTRAL. An application that has not been validated cannot be electronically submitted.
- If any modifications are made to the proposal during the signature process, make certain the electronic and paper versions are consistent.
- Technical questions regarding the electronic application process should be directed to Altum at <https://proposalcentral.com/> or 1-800-875-2562.
- Electronic applications must be submitted on proposalCENTRAL by close of business (5:00 PM ET) on the specified deadline date. If the deadline falls on a weekend or holiday, applications will be accepted the following business day.

Note: After submission, you will not be able to make any changes to the forms or upload any modifications to the files.

B. PAPER COPY

A single paper copy of the application must be received by the ACS Global Headquarters no later than 5:00 PM (ET) on the next business day following the deadline date for the electronic submission, shifted as needed to account for weekends or holidays.

- The paper copy must include the signatures (front page) and contact information (second page) of the:
 - Applicant
 - Institutional Official
 - Department Head

- Original signatures are not required; electronic signatures are acceptable. See program-specific instructions for additional required signatures. Please confirm that all required signatures have been collected before mailing the paper copy.
- Print application via proposalCENTRAL. (“Print” on the menu > select “Print Signature Pages and Attached PDF Files”). *Do not print cover pages for an application before validation.*
- Note that cover pages are not uploaded to proposalCENTRAL but are mailed with your paper version.

Secure the application with a rubber band or clip rather than staples, and mail only one application per package to:

**The American Cancer Society
Extramural Research Department
250 Williams Street NW
Atlanta, GA 30303
404-329-7558**

B. PREPARING THE APPLICATION

1. COVER PAGES

Complete all fields, which include mandatory signatures for the principal investigator, primary mentor, department chair (or equivalent), and institutional official. If you have received a letter from the ACS Eligibility Committee, indicate that in the Program Eligibility information section and upload the correspondence in the Appendix. See Part A General Instructions for more details.

2. APPLICATION TEMPLATES

Once an application is started on ProposalCENTRAL, all necessary application templates are available to download. Complete off-line (described in individual sections below) and upload as .pdf documents before submitting the online application. *For assistance, see proposalCENTRAL’s FAQ or call support at 1-800-875-2562.*

3. TABLE OF CONTENTS (PAGE 1.1)

Complete the Table of Contents by indicating the appropriate page numbers for the Research Plan section; limit the length of the Table of Contents to two pages.

4. BIOGRAPHICAL SKETCH OF APPLICANT (PAGE 2.1)

Complete the NIH Biosketch template. NOTE: The Biographical Sketch may not exceed five pages. Follow the formats and instructions provided by the NIH.

5. REPLY TO PREVIOUS REVIEW (RESUBMISSIONS ONLY) (PAGE 3.1)

IF APPLICATION IS A NEW SUBMISSION upload the provided template with “Not Applicable” in the body.

All resubmissions must create a new application on proposalCENTRAL.

For Resubmissions: Address the points raised in the previous critiques and direct the reviewer to the specific sections of the text where edits have been made. Revisions should be easily identifiable in the revised application (e.g.: bold type, italicized, or underline type). This section should not exceed 3 pages.

6. PREVIOUS CRITIQUES (RESUBMISSIONS ONLY)

Electronic copies of the critiques for your 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.

7. RESEARCH PLAN AND ENVIRONMENT (PAGE 4.1)

Section A below (Specific Aims) should not exceed 1 page. Sections B-F below must not exceed 5 pages. This page limit does not include Experimental Details (G) Environment (H), the Statement of Science Outreach and Advocacy (I), or the References (J).

The same proposal may be submitted to multiple funding agencies on an “either/or” basis, but ACS proposals must conform to our guidelines (including term and budget constraints). If not, a proposal may be returned without review.

A. Hypothesis and Specific Aims. List the hypotheses, objectives, and goals of the research proposed and describe the specific aims briefly. In addition, state the anticipated impact of the research on one of more of the following areas: improving and managing pain or other distressing symptoms, improving quality of life, or fostering effective communication between cancer survivors, their families and their health care providers; or testing novel models of delivering palliative care or system level intervention to improve access, care coordination or outcomes for cancer patients and their families.

B. Background and Significance Background and Significance. Concisely summarize and critically evaluate related work done by others. Specifically state how the successful completion of the work proposed in the specific aims will advance scientific knowledge or aspects of clinical practice that are important for a better understanding of cancer or management of cancer patients. The critique of the literature should also include pertinent evidence-based

interventions that inform your approach. Additionally, the theoretical model(s) that underpins the research approach and forms the basis of your conceptual framework should be summarized here.

C. Statement of Cancer Relevance (limit to 250 words. This does not count towards the 5 page limit). This section is important to the stakeholders (non-scientific members) on the peer review committees as well as to several general audiences, including donors. **Avoid the use of technical jargon.**

Describe how the project contributes short- and long-term to the control of cancer. Specifically, improving symptom management, quality of life, quality of care or fostering effective communication between cancer survivors, their families and their health care providers patients.

D. Innovation

1. If applicable, explain how the application challenges and seeks to shift current research or clinical-practice paradigms.
2. Describe any novel theoretical concepts, approaches, methodologies, instrumentation, or intervention(s) to be developed or used, and the advantage they offer over existing ones.
3. Explain any refinements, improvements, or new applications of theoretical concepts, approaches, methodologies, instrumentation, or interventions.

E. Preliminary Studies. Provide results of your prior research that are relevant to this proposal; reprints or preprints may be included in the Appendix. Note that the entire application is considered confidential.

F. Research Design. Describe your overall hypothesis, proposed methods, procedures, and data analysis in sufficient detail to permit evaluation by other scientists; include your rationale for approaches and analysis. Explain your project's feasibility and how the experiments proposed will address the Specific Aims.

Discuss potential difficulties and limitations of your proposed methods and provide alternative approaches. Inclusion of an experimental time-line can be helpful.

Experimental Details (optional – not to exceed 3 pages). This section is available if more in-depth description of the experimental design, technologies, or assays are needed to convey the specific approaches and procedures proposed.

G. Environment. Describe the space and equipment available to conduct the proposed research (e.g., space designated specifically for your research program, shared space and/or core facilities). The required signature on the cover page by the Department Chair or equivalent verifies an institutional commitment of described research facilities. A detailed description of space and equipment is especially important for non-tenure-track applicants.

H. Statement of Science Outreach and Advocacy (not to exceed 1 page).

The ACS considers it important that scientists communicate the results of their research to a wide range of communities. Explain the potential impact of your proposed project on your community, and to the ACS's mission of eliminating cancer as a major health problem. Share any previous experiences in science outreach and advocacy. Describe your future plans for disseminating your work in the cancer arena through advocacy, awareness, education, or service. Please include your plans for sharing your research and findings with your non-academic community members and for engaging with community partners in the dissemination process.

I. References. Each literature citation should include title, authors, book or journal, volume number, page numbers, and year of publication. There is no page limitation; this section is not included in the 5 page limit of Sections (B) through (F).

8. DETAILED BUDGET

Complete the budget page located online at proposalCENTRAL

A. Personnel. Names and positions of all key personnel must be individually listed and the percentage of time to be devoted to the project by each person should be noted. List all key personnel other than the PI (defined as individuals who will participate actively in the design and/or execution of the studies). Details of contractual arrangements with key personnel should be provided in the Justification of Budget section of the application.

If the individual has not been selected, please list as "vacancy." Personnel may receive salary support up to a maximum that equals the National Cancer Institute salary cap, prorated according to their percent effort on the project.

The costs to the institution of employee fringe benefits should be indicated as a percent of the employee's salary. The amount of fringe benefits requested must be prorated to the salary requested. (For example, if 50 percent of an individual's annual salary is requested then no more than 50 percent of that individual's annual cost for fringe benefits can be requested.)

Please Note: For definitions of key personnel refer to section 4.

B. Equipment.

- **Permanent equipment** - Defined as items of nonexpendable property with a purchase cost per unit that equals or exceeds \$5,000 with a useful life of more than one year. List separately and justify the need for each item of permanent equipment. Note: the cost of permanent equipment is not included in the Direct Cost total used to calculate Indirect Costs.

- **Small or expendable equipment** is defined as expendable property with a purchase cost per unit less than \$5,000 with a service life of less than 1 year). Note: the cost of small or expendable equipment may be included in the Direct Cost total used to calculate Indirect Costs.
 - **General purpose equipment** - Equipment such as computers used primarily or exclusively in the actual conduct of the proposed scientific project are considered direct cost and may be included in the Direct Cost total used to calculate Indirect Costs. Computers or other general-purpose equipment that will be used on multiple projects or for personal use should not be listed as a direct cost and should not be included in the calculation for indirect cost.
- C. Supplies.** Group supplies into major categories (glassware, chemicals, radioisotopes, survey materials, animals, etc.).
- D. Travel.** Domestic travel only: special consideration will be given for attendance at scientific meetings held in Canada.

Recipients of PEP in Palliative Care grants are required to attend the National Palliative Care Research Center's (NPCRC's) Annual Kathleen Foley Palliative Care Retreat and Research Symposium meeting in years 1 and 2 of the grant term. The meeting is held in September/October of each year. Principal investigators are responsible for airfare and lodging for the conference and should budget a minimum of \$1,500 per year.

- E. Miscellaneous Expenditures.** List specific amounts for each item. Examples of allowed expenditures include publication costs and special fees (e.g., publication costs, pathology, computer time and scientific software, and equipment maintenance).
- F. Subcontracts.** If any portion of the proposed research is to be carried out at another institution, enter the total costs (direct) on to the online budget detail page on proposalCentral. Then provide a categorical breakdown of costs using the Subcontractor Budget and Justification form, using one form per subcontractor. Upload the form(s) when complete, entering subcontractor name in the "describe attachment" field. Note: indirect costs for the subcontract budget may be claimed by either the primary or the secondary institution, but not both.

Subcontracts for the research project may be with public or private institutions, provided they do not violate ACS policies. Subcontracts involving a contractor residing outside the borders of the United States are not permitted, unless the applicant can document that it is not feasible to have the work performed within the United States. Use of any subcontractor outside of the United States must be approved in writing by ACS prior to the performance of any work funded by the ACS grant.

Administrative pages: A Letter of Agreement pertaining to the subcontract should be included in the Appendix.

G. Indirect Costs. To help the institution provide proper laboratory and clinical facilities, the Society will permit an indirect cost allowance of up to 20% of the direct costs, excluding permanent equipment. Indirect costs for a subcontract budget may be claimed by either the primary or the secondary institution, but not both. Indirect costs can be provided to the secondary institution through negotiation with the Principal Investigator's institution but the total amount of indirect costs, inclusive of subcontracts, may not exceed 20% of the award.

H. Total Amount Requested. Budget totals should reflect a maximum duration of 2 years. Enter the sum of all years of requested support including indirect costs, and round to the nearest thousand dollars. Transfer this figure to the title page of the online application.

9. JUSTIFICATION OF BUDGET

Provide budget justification on the template provided. Justify all items of permanent equipment costing over \$5,000, as well as your needs for personnel, supplies, travel, and other miscellaneous items. If the budget includes a request for funds to be spent outside the United States or its territories, explain why these funds are essential to the successful conduct of the project, and why there are no alternatives. Provide details of contractual arrangements with key personnel in this section.

10. BIOGRAPHICAL INFORMATION OF KEY PERSONNEL (PAGE 5.1)

Provide information for all key personnel involved in the project. Complete the NIH Biosketch template. **NOTE: Follow the format and instructions provided by NIH.**

11. OTHER SUPPORT (PAGE 6.1)

The American Cancer Society does not fund projects that are supported all or in part by another agency. Projects are considered to overlap if there are any shared *Specific Aims or areas of budgetary overlap*. The peer review committees make final decisions regarding any questions of overlap.

The only exceptions are:

- funds provided by the institution as start-up support to develop a new laboratory or to gather pilot data; and
- awards that provide only salary support for the Principal Investigator. In the latter case, if the salary support for the PI's contribution to the project is covered by the other agency, no additional salary support for the PI may be requested from the American Cancer Society.

Provide the following information separately for the Principal Investigator and all other Key Personnel:

- 1. Current Support.** List all current funding from intramural and extramural sources (e.g., institutional awards and grants from for-profit and not-for-profit agencies, including other grants from the American Cancer Society). Provide for each award:
 - a. Source of funds: the organization providing the support
 - b. Grant number
 - c. Project title
 - d. Inclusive dates of approved or proposed project. For example, in the case of NIH support, provide the dates of the approved or proposed competitive segment.
 - e. Total direct costs
 - f. Percent effort or person-months. For an active project, use person months, even if unsalaried, for the current budget period. Classify person-months as academic, calendar, and/or summer.
 - g. An outline of the goals of the project in a brief paragraph.
 - h. A clear indication of overlap and differences between this grant and the proposed study. If necessary, include an explanatory letter in the Appendix.

- 2. Pending Support.** List all pending applications for funding from intramural and extramural sources (e.g., institutional awards and grants from for-profit and not-for-profit agencies, including other grants from the American Cancer Society). Provide for each award:
 - a. Source of funds: the organization providing the support
 - b. Grant number
 - c. Project title
 - d. Inclusive dates of approved or proposed project. For example, in the case of NIH support, provide the dates of the approved or proposed competitive segment.
 - e. Total direct costs
 - f. Percent effort or person-months. For an active project, use person months, even if unsalaried, for the current budget period. Classify person-months as academic, calendar, and/or summer.
 - g. An outline of the goals of the project in a brief paragraph.
 - h. A clear indication of overlap and differences between this grant and the proposed study. If necessary, include an explanatory letter in the appendix. In such cases, you may accept only 1 award if both are approved for funding.

Specific Aims Specific Aims

Please keep the Scientific Director current on the status of pending applications that have scientific overlap, or could compromise eligibility (i.e., receipt of funding for a grant that has overlapping aims

- 3. Institutional Support.** Provide the following information for the Principal Investigator only:
- a. A description of any start-up funds provided by the institution to the applicant. An award of start-up funds does not decrease the likelihood of ACS support, and can be important evidence of institutional commitment.
 - b. Details of the institutional commitment to support the applicant's salary.
 - c. The current term of the applicant's appointment.

Applicants not on tenure track should also include a more detailed description of the space committed to the project. If the applicant is in the same department as a previous mentor, provide information on the relationship between the mentor's research space, and the space available for the project; and the relationship between funded research projects in the mentor's laboratory and the present application.

Please upload a letter from the Department Chair or equivalent that clearly indicates the institution's commitment to support the applicant and their research program. Details should include salary support, dedicated space, startup funds, and others as appropriate. Clinician scientists should include a description of their clinical practice (discipline and clinical responsibilities) as well as the amount of protected time.

12. LIST OF LETTERS OF SUPPORT FROM COLLABORATORS/CONSULTANTS (PAGE 7.1)

Provide a list of collaborators and consultants. Then directly upload the letter from each individual collaborator or consultant after page 7.1. The letter should outline the role that person will play with sufficient detail for evaluation of the value of the individual contribution.

13. COMPLIANCE STATEMENTS (PAGE 8.1-8.2)

Human Subjects

Selection of study population. When conducting research on humans, provide the rationale for selecting your target population. Include the involvement of children, minorities, and especially vulnerable populations such as neonates, pregnant women, prisoners, institutionalized individuals, or Specific Aims. IRB approval is required prior to activation of a grant.

On the planned enrollment form estimate the total number of subjects by primary ethnicity and race, race/ethnicity subgroup (if applicable), and gender. Include a rationale for excluding any population. Estimate the planned enrollment based on these calculations.

Also include estimates of the sample distribution by gender, race, and ethnicity (if available). For example, if your sample size is 200, to complete the *total number of subjects* column by race (based on what you know about the population demographics or the existing dataset you plan to analyze), multiple by the estimated percentage.

Estimated percentage of the population by race	Estimated total number of subjects
50% White	100 (200 x 0.50)
49% AA	98 (200 x 0.49)
1% Asian	2 (200 x 0.01)

For applicants performing research with non-human subjects, check the box that most appropriately describes your research.

Potential benefits, risks, and knowledge gained. Succinctly describe the potential benefits and risks to subjects (physical, psychological, financial, legal, or other). Explain why the risks are reasonable in relation to the anticipated benefits, both to research participants and others. Where appropriate, describe alternative treatments and procedures, including the risks and potential benefits to participants of those.

Research Specimens and Data. If the proposed research involves bio-specimens, explain how the research material will be obtained from living subjects and what materials will be collected. List any specific non-biological data, such as demographic information, and how it will be collected, managed, and protected. Specify who will have access to such data and what measures you will maintain to keep personally identifiable private information confidential.

Collaborating sites. List any collaborating sites where research on human subjects will be performed and describe the role of those sites and collaborating investigators in performing the proposed research. Explain how data from the site(s) will be obtained, managed, and protected.

*For additional protections for vulnerable populations, see <http://www.hhs.gov/ohrp/policy/populations/index.html>.

14. APPENDIX TO APPLICATION

In addition to the application templates, other key documents may be uploaded and submitted as part of the application. However, applicants are urged to keep this section as brief as possible.

Appended materials may include:

- Letter from ACS Eligibility Committee confirming eligibility (if applicable)
- Letters of support
- Recent reprints or preprints (optional)
- Clinical Protocols (if applicable)
- Logic Model (for program projects and dissemination and implementation pilots – if applicable)

It is not necessary to number the pages of the appendix, but please list by categories (i.e., reprints, preprints, etc.) in the Table of Contents of the application.

APPENDIX A: CLASSIFICATION CATEGORIES - AREAS OF RESEARCH

The areas of research are based on seven broad categories called the Common Scientific Outline (CSO) developed by the International Cancer Research Partnership (ICRP):

1. Biology
2. Etiology
3. Prevention
4. Early Detection, Diagnosis and Prognosis
5. Treatment
6. Cancer Control, Survivorship and Outcomes Research

Applicants are asked to select from the following codes:

1 – BIOLOGY

Research included in this category looks at the biology of how cancer starts and progresses as well as normal biology relevant to these processes.

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
- Characterization of pluripotent progenitor cells (e.g., normal stem cells)

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.
- Research into the biology of stem cell tumour initiation

1.4 Cancer Progression and Metastasis

Examples of science that would fit:

- 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 extravasation
- Systemic and cellular effects of malignancy
- Tumor angiogenesis and growth of metastases
- Role of hormone or growth factor dependence/independence in cancer progression
- Research into cancer stem cells supporting or maintaining cancer progression

1.5 Resources and Infrastructure

Examples of science that would fit:

- Informatics and informatics networks
- Specimen resources
- Epidemiological resources pertaining to biology
- Reagents, chemical standards
- Development and characterization of new model systems for biology, distribution of models to scientific community or research into novel ways of applying model systems, including but not limited to computer-simulation systems, software development, in vitro/cell culture models, organ/tissue models or animal model systems. Guidance note: this should only be used where the focus of the award is creating a model. If it is only a tool or a methodology, code to the research instead.
- Education and training of investigators at all levels (including clinicians and other health professionals), such as participation in training workshops, conferences, advanced research technique courses, and Master's course attendance. This does not include longer-term research-based training, such as Ph.D. or post-doctoral fellowships.

2 – ETIOLOGY

Research included in this category aims to identify the causes or origins of cancer - genetic, environmental, and lifestyle, and the interactions between these factors.

2.1 Exogenous Factors in the Origin and Cause of Cancer

Examples of science that would fit:

- Research into the role of lifestyle factors such as smoking, chewing tobacco, alcohol consumption, parity, diet, sunbathing, and exercise in the origin and cause of cancer or increasing the risk of cancer
- Research into the social determinants of cancer such as crime, housing dilapidation, neighbourhood level socioeconomic status and services and their relationship to cancer incidence and mortality etc.
- Studies on the effect(s) of nutrients or nutritional status on cancer incidence
- Development, characterization, validation, and use of dietary/nutritional assessment instruments in epidemiological studies and to evaluate cancer risk
- 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
- Contextual Factors Contributing to Cancer Incidence (e.g., race/ethnicity, socioeconomic status, neighborhood factors, community factors, built environment).

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
- Identification /confirmation of genes suspected of being mechanistically involved in familial cancer syndromes; for example, BRCA1, Ataxia Telangiectasia, and APC
- Identification/confirmation of 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.)
- Investigating a role for stem cells in the etiology of tumours

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

Examples of science that would fit:

- 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
- Development, characterization and validation of new model systems for etiology, distribution of models to the scientific community or research into novel ways of applying model systems, including but not limited to computer-simulation systems, software development, in vitro/cell culture models, organ/tissue models or animal model systems. Guidance note: this should only be used where the focus of the award is creating a model. If it is only a tool or a methodology, code to the research instead.
- Education and training of investigators at all levels (including clinicians and other health professionals), such as participation in training workshops, conferences, advanced research technique courses, and Master's course attendance. This does not include longer term research based training, such as Ph.D. or post-doctoral fellowships.

3 – PREVENTION

Research included in this category looks at identifying individual and population-based primary prevention interventions, which reduce cancer risk by reducing exposure to cancer risks and increasing protective factors.

3.1 Interventions to Prevent Cancer: Personal Behaviors (Non-Dietary) that Affect Cancer Risk

Examples of science that would fit:

- Research on determinants of personal behaviors, such as physical activity, sun exposure, and tobacco use, known to affect cancer risk and interventions (including educational and behavioral interventions directed at individuals as well as population-based interventions including social marketing campaigns, environmental supports, and regulatory, policy and legislative changes) to change determinants
- Directed education to specified populations of patients, health care providers, and at-risk groups about cancer risk and prevention and relevant interventions with the intent of

promoting increased awareness and behavioral change. This includes communication of lifestyle models that reduce cancer risk, such as communicating smoking and tobacco cessation interventions

3.2 Dietary Interventions to Reduce Cancer Risk and Nutritional Science in Cancer Prevention

Examples of science that would fit:

- Quantification of nutrients, micronutrients, and purified nutritional compounds in cancer prevention studies
- Development, characterization, validation, and use of dietary/nutritional assessment instruments to evaluate cancer prevention interventions
- Research on determinants of dietary behavior and interventions to change diet (including educational and behavioral interventions directed at individuals as well as population-based interventions including social marketing campaigns, environmental supports, and regulatory and legislative changes) to change diet
- Education of patients, health care providers, at-risk populations, and the general population about cancer risk and diet
- Communicating cancer risk of diet to underserved populations, at-risk populations, and the general public
- Communication of nutritional interventions that reduce cancer risk"

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 (e.g., HPV vaccines)
- Guidance note: only preventive/prophylactic vaccine research should be included here. Vaccines for the treatment of cancer should be coded to 5.3 or 5.4, depending on the phase of development.

3.5 Complementary and Alternative Prevention Approaches

Examples of science that would fit:

- Discovery, development, and testing of complementary/alternative medicine (CAM) approaches or other primary prevention interventions that are not widely used in conventional medicine or are being applied in different ways as compared to conventional medical uses

- Mind and body medicine (e.g., meditation, acupuncture, hypnotherapy), manipulative and body-based practices (e.g., spinal manipulation, massage therapy), and other practices (e.g., light therapy, traditional healing) used as a preventive measure.

3.6 Resources and Infrastructure Related to Prevention

Examples of science that would fit:

- 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
- Development and characterization of new model systems for prevention, distribution of models to scientific community or research into novel ways of applying model systems, including but not limited to computer-simulation systems, software development, in vitro/cell culture models, organ/tissue models or animal model systems. Guidance note: this should only be used where the focus of the award is creating a model. If it is only a tool or a methodology, code to the research instead.
- Education and training of investigators at all levels (including clinicians and other health professionals), such as participation in training workshops, conferences, advanced research technique courses, and Master's course attendance. This does not include longer term research based training, such as Ph.D. or post-doctoral fellowships.

4 – EARLY DETECTION, DIAGNOSIS, AND PROGNOSIS

Research included in this category focuses on identifying and testing cancer markers and imaging methods that are helpful in detecting and/or diagnosing cancer as well as predicting the outcome or chance of recurrence or to support treatment decision making in stratified/personalised medicine.

4.1 Technology Development and/or Marker Discovery

Examples of science that would fit:

- Discovery or identification and characterization of markers (e.g., proteins, genes, epigenetic), 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 or identification of markers

- Defining molecular signatures of cancer cells, including cancer stem cells (e.g., for the purposes of diagnosis/prognosis and to enable treatment decision planning in personalized/stratified/precision medicine)

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, preclinical, and Phase I human trials) of identified markers or technologies such as genetic/protein biomarkers (prospective or retrospective) or imaging methods (optical probes, PET, MRI, etc.)
- Preliminary evaluation with respect to laboratory sensitivity, laboratory specificity, reproducibility, and accuracy
- Retrospective studies of existing sample collections and evaluation of markers in ancillary studies
- 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

Examples of science that would fit:

- 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, and receiver-operator characteristics. Includes education, communication, behavioral and complementary/alternative approaches to improve compliance, acceptability or to reduce anxiety/discomfort.
- 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

- Development, characterization and validation of new model systems for detection, diagnosis or prognosis, distribution of models to the scientific community or research into novel ways of applying model systems, including but not limited to computer-simulation systems, software development, in vitro/cell culture models, organ/tissue models or animal model systems. Guidance note: this should only be used where the focus of the award is creating a model. If it is only a tool or a methodology, code to the research instead.
- Education and training of investigators at all levels (including clinicians and other health professionals), such as participation in training workshops, conferences, advanced research technique courses, and Master's course attendance. This does not include longer term research based training, such as Ph.D. or post-doctoral fellowships.

5 – TREATMENT

Research included in this category focuses on identifying and testing treatments administered locally (such as radiotherapy and surgery) and systemically (treatments like chemotherapy which are administered throughout the body) as well as non-traditional (complementary/alternative) treatments (such as supplements, herbs). Research into the prevention of recurrence and treatment of metastases are also included here.

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, cryotherapy, local/regional hyperthermia, high-intensity, focused ultrasound, radiotherapy, and brachytherapy
- Therapies with a component administered systemically but that act locally (e.g., photodynamic therapy, radioimmunotherapy and radiosensitizers)
- Development of methods of localized drug delivery
- Research into the development of localized therapies to prevent recurrence
- Guidance note: localized therapies are considered to be localized when the site of action is the same as the site of administration.

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, cryotherapy, local/regional hyperthermia, radiotherapy, and brachytherapy.
- 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
- Clinical testing of localized therapies to prevent recurrence and prevent and treat metastases
- Guidance note: localized therapies are considered to be localized when the site of action is the same as the site of administration.

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 (treatment vaccines, antibodies), gene therapy, angiogenesis inhibitors, apoptosis inhibitors, whole body hyperthermia, bone marrow/stem cell transplantation, differentiating agents, adjuvant and neo-adjuvant treatments
- Identifying mechanisms of action of existing cancer drugs and novel drug targets, including cancer stem cells for the purposes of treatment/identifying drug targets
- Drug discovery and development, including drug metabolism, pharmacokinetics, pharmacodynamics, combinatorial chemical synthesis, drug screening, development of high throughput assays, and testing in model systems, including that which may aid treatment planning in stratified/personalised medicine
- Investigating the molecular mechanisms of drug resistance (including the role of cancer stem cells) and pre-clinical evaluation of therapies to circumvent resistance
- Development of methods of drug delivery
- Research into the development of systemic therapies to prevent recurrence

5.4 Systemic Therapies - Clinical Applications

Examples of science that would fit:

- Clinical testing and application of treatments administered systemically such as cytotoxic or hormonal agents, novel systemic therapies such as immunologically directed therapies (treatment vaccines, antibodies), gene therapy, angiogenesis inhibitors, apoptosis inhibitors, whole body hyperthermia, bone marrow/stem cell transplantation, and differentiating agents
- Phase I, II, or III clinical trials of promising therapies administered systemically
- Side effects, toxicity, and pharmacodynamics
- Clinical testing of systemic therapies to prevent recurrence and prevent and treat metastases

5.5 Combinations of Localized and Systemic Therapies

Examples of science that would fit:

- Development and testing of combined local and systemic approaches to treatment (e.g., radiotherapy and chemotherapy, or surgery and chemotherapy)
- Clinical application of combined approaches to treatment such as systemic cytotoxic therapy and radiation therapy
- Development and clinical application of combined localized and systemic therapies to prevent recurrence and prevent and treat metastases

5.6 Complementary and Alternative Treatment Approaches

Examples of science that would fit:

- Discovery, development, and clinical application of complementary/alternative medicine (CAM) treatment approaches such as diet, herbs, supplements, natural substances, or other interventions that are not widely used in conventional medicine or are being applied in different ways as compared to conventional medical uses
- Complementary/alternative or non-pharmaceutical approaches to prevent recurrence and prevent and treat metastases

5.7 Resources and Infrastructure Related to Treatment and the Prevention of Recurrence

Examples of science that would fit:

- Informatics and informatics networks; for example, clinical trials 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
- Development and characterization of new model systems for treatment, distribution of models to scientific community or research into novel ways of applying model systems, including but not limited to computer-simulation systems, software development, in vitro/cell culture models, organ/tissue models or animal model systems. Guidance note: this should only be used where the focus of the award is creating a model. If it is only a tool or a methodology, code to the research instead.
- Reviews/meta-analyses of clinical effectiveness of therapeutics/treatments
- Education and training of investigators at all levels (including clinicians and other health professionals), such as participation in training workshops, conferences, advanced research technique courses, and Master's course attendance. This does not include longer term research based training, such as Ph.D. or post-doctoral fellowships.

6 - CANCER CONTROL, SURVIVORSHIP, AND OUTCOMES RESEARCH

Research included in this category includes a broad range of areas: patient care and pain management; tracking cancer cases in the population; beliefs and attitudes that affect behavior regarding cancer control; ethics; education and communication approaches for patients, family/caregivers, and health care professionals; supportive and end-of-life care; and health care delivery in terms of quality and cost effectiveness.

6.1 Patient Care and Survivorship Issues

Examples of science that would fit:

- Research into patient-centered outcomes
- Quality of life
- Pain management
- Psychological impacts of cancer survivorship
- Rehabilitation, including reconstruction and replacement
- Economic sequelae, including research on employment, return to work, and vocational/educational impacts on survivors and their families/caregivers
- Reproductive issues
- Long-term issues (morbidity, health status, social and psychological pathways)
- Symptom management, including nausea, vomiting, lymphedema, neuropathies, etc.
- Prevention and management of long-term treatment-related toxicities and sequelae, including symptom management (e.g., physical activity or other interventions), prevention of mucosities, prevention of cardiotoxicities, opportunistic infections, etc.
- Psychological, educational or complementary/alternative (e.g., hypnotherapy, relaxation, transcendental meditation, imagery, spiritual healing, massage, biofeedback, herbs, spinal manipulation, yoga, acupuncture) interventions/approaches to promote behaviors that lessen treatment-related morbidity and promote psychological adjustment to the diagnosis of cancer and to treatment effects
- Burdens of cancer on family members/caregivers and interventions to assist family members/caregivers
- Educational interventions to promote self-care and symptom management
- Research into peer support, self-help, and other support groups
- Behavioral factors in treatment compliance

6.2 Surveillance

Examples of science that would fit:

- Epidemiology and end results reporting (e.g., SEER)
- Registries that track incidence, morbidity, co-morbidities/symptoms, long-term effects and/or mortality related to cancer

- Surveillance of established cancer risk factors in populations such as diet, body weight, physical activity, sun exposure, and tobacco use
- Analysis of variations in established cancer risk factor exposure in populations by demographic, geographic, economic, or other factors
- Trends in use of interventional strategies in populations (e.g., geographic variation)

6.3 Population-based Behavioral Factors

Examples of science that would fit:

- Research into populations' attitudes and belief systems (including cultural beliefs) and their influence on behaviors related to cancer control, outcomes and treatment. For example, how populations' beliefs can affect compliance/interaction with all aspects of the health care/service provision

6.4 Health Services, Economic and Health Policy Analyses

Examples of science that would fit:

- 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 to care and quality of care, including studies on variations or inequalities in access among racial, ethnic, geographical or socio-economic groups
- 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
- Health services research, including health policy and practice
- Analysis of health service provision, including the interaction of primary and secondary care
- Analyses of the cost effectiveness of methods used in cancer prevention, detection, diagnosis, prognosis, treatment, and survivor care/support

6.5 Education and Communication Research

Examples of science that would fit:

- Development of generic health provider-patient communication tools and methods (e.g., telemedicine/health)
- Tailoring educational approaches or communication to different populations (e.g., social, racial, geographical, or linguistic groups)
- Research into new educational and communication methods and approaches, including special approaches and considerations for underserved and at-risk populations
- Research on new methods and strategies to disseminate cancer information/innovation to healthcare providers (e.g., web-based information, telemedicine, smartphone apps, etc.) and the effectiveness of these approaches

- Research on new communication processes and/or media and information technologies within the health care system and the effectiveness of these approaches
- Media studies focused on the nature and ways in which information on cancer and cancer research findings are communicated to the general public
- Education, information, and assessment systems for the general public, primary care professionals, or policy makers
- Research into barriers to successful health communication

6.6 End-of-Life Care

Examples of science that would fit:

- Hospice/end-of-life patient care focused on managing pain and other symptoms (e.g., respiratory distress, delirium) and the provision of psychological, social, spiritual and practical support through either conventional or complementary/alternative interventions/approaches throughout the last phase of life and into bereavement
- Quality of life and quality of death for terminally-ill patients
- Provision of psychological, social, spiritual and practical support to families/caregivers through either conventional or complementary/alternative interventions/approaches
- Research into the delivery of hospice care

6.7 Research on Ethics and Confidentiality

Examples of science that would fit:

- Informed consent modeling/framing and development
- Quality of Institutional Review Boards (IRBs)
- Protecting patient confidentiality and privacy
- Research ethics
- Research on publication bias within the cancer research field

6.8 – Historical code [no longer used]

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 pertaining to cancer control, survivorship and outcomes research
- Surveillance infrastructures
- Centers, consortia, and/or networks pertaining to cancer control, survivorship and outcomes research

- Development and characterization of new model systems for cancer control, outcomes or survivorship, distribution of models to scientific community or research into novel ways of applying model systems, including but not limited to computer-simulation systems, software development, in vitro/cell culture models, organ/tissue models or animal model systems. Guidance note: this should only be used where the focus of the award is creating a model. If it is only a tool or a methodology, code to the research instead.
- Psychosocial, economic, political and health services research frameworks and models
- Education and training of investigators at all levels (including clinicians and other health professionals), such as participation in training workshops, conferences, advanced research technique courses, and Master's course attendance. This does not include longer-term research-based training, such as Ph.D. or post-doctoral fellowships.

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, results 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: REVIEWER GUIDELINE CRITERIA

Provided below are the guidelines used by reviewers to evaluate PEP applications. These are meant as general guidelines and are provided here as an aid for preparing your application.

PART I CANDIDATE

Investigator:

Provide an overall evaluation of the candidate's academic, clinical, or scientific qualifications as well as their potential to succeed as an independent investigator and commitment to a career in cancer-related research. Describe the qualifications of the applicant giving consideration to the following items: goals and commitment to cancer-related research; past education; past training – board eligible or board certified, if appropriate; past research experience; number and relevance of previous publications; and overall appropriateness of candidate for the PEP. The PEP award is intended for fully independent scientists with clear evidence of institutional commitment (e.g. tenure-track, start-up funds, independent space, senior author publications) as confirmed in the Letter of Support from their Department Chair (in grant application STATEMENT OF INSTITUTIONAL SUPPORT). Any comments related to independence would be included here.

PART II RESEARCH PLAN

Reply to Previous Review:

REPLY TO PREVIOUS REVIEWS [IF APPLICABLE]: Note whether this is a resubmission and comment on adequacy of response to critiques.

In critiquing the research plan, please be as specific and as detailed as possible. Comments should include, but are not limited to, a discussion of the following elements:

1. **SIGNIFICANCE:** Does the project address an important problem or a critical barrier to progress in the field? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice improve? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?
2. **CANCER RELEVANCE:** How is this research relevant or how will it impact persons at risk for, or living with, cancer and their family members and/or caregivers? The relevance to cancer may be indirect, but the connection must be clearly articulated by the applicant.
3. **INNOVATION/IMPROVEMENT:** What is the potential that the proposed study will challenge and seek to shift current research understanding or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Does the research propose meaningful improvements or address critical gaps?

4. INVESTIGATOR/ RESEARCH TEAM: Does the PI and research team have the training and experience needed to carry out the proposed research?
5. APPROACH: Are study design, methods for implementation, data collection and analysis appropriate for answering the research question(s). Where appropriate, are proposed recruitment and/or case ascertainment methods well developed? Is the sample size adequate? Is the research timeline realistic and future plans articulated?
6. ENVIRONMENT: Will the scientific environment and institutional support contribute to the probability of success? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements? Provide a description of any start-up funds available to support the candidate.

PART III BUDGET

Evaluate the overall budget and individual budget categories with respect to the award cap and the project aims. Are the budget items justified, specified, and accurate? Is the project duration and PI percent effort appropriate? Is there a potential overlap with the PI's other funded research? Describe any suggested budget changes- use specific amounts and/or percentages.

JUSTIFICATION OF BUDGET

Key Project Personnel: Please provide one or two sentences per individual describing qualifications of the applicant, collaborators, consultants, and relevant staff for proposed research project.

Research Materials and Animals: Make specific and/or broad recommendations for changes when proposed items/amounts are not appropriate. Do not include budget concerns in evaluation of the merit of a proposal; rating should be based solely on technical and scientific merit.

Other support: Examine any issues of overlap.

PART IV COMPLIANCE STATEMENTS

1. Human Subjects. If the project involves research on humans, are the plans for protection of human subjects from research risks justified in terms of the scientific goals and research strategy proposed? For example, are the potential benefits & risks to subjects articulated reasonable and appropriate given the study design, are there plans to conduct sub-analysis by group, are there plans for data security and confidentiality, biohazards and data and safety monitoring (if applicable) adequate.
2. Inclusion of Women, Minorities, and Children. When the proposed project involves human subjects, evaluate the adequacy of the proposed plans for inclusion or exclusion of minorities, male and female genders, as well as children.
3. Vertebrate Animals. The peer review committee will evaluate the involvement of live, vertebrate animals as part of the scientific assessment according to the following points: 1) necessity for the use of the animals and species proposed; 2) appropriateness of the strains, ages, and gender of the animals to be used for the experimental plan proposed; 3) justifications for, and appropriateness of, the numbers used for the experimental plan proposed.

4. Biohazards. Reviewers will assess whether materials or procedures proposed are potentially hazardous to research personnel and/or the environment, and if needed, determine whether adequate protection is proposed.