

AMERICAN CANCER SOCIETY

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

AND

**PILOT AND EXPLORATORY STUDIES USING COMMUNITY-BASED PARTICIPATORY
RESEARCH (CBPR) TO ACHIEVE CANCER HEALTH EQUITY**

POLICIES AND INSTRUCTIONS

EFFECTIVE January 2015

ELECTRONIC APPLICATION DEADLINE: APRIL 1, 2015

PAPER APPLICATION COPY DEADLINE: APRIL 2, 2015

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

PILOT AND EXPLORATORY PROJECT

POLICIES

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

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

Each year, the Society receives approximately 2,000 requests for support of cancer research and for training of health care professionals. All proposals are subjected to multiple levels of rigorous and 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 19.

GRANT MECHANISMS

RESEARCH GRANTS FOR INDEPENDENT INVESTIGATORS

Research Scholar Grants— Applicants must be independent, self-directed researchers within six years of their first academic appointment. The maximum award is for 4 years and for as much as \$165,000 per year (direct costs), plus 20% allowable indirect costs.

The only eligibility exception is in the Priority Focus on Health Equity Research in the Cancer Control and Prevention Research Program, which is restricted to: research studies in psychosocial, behavioral, health policy or health services which address cancer health equity and disparities. In this case, investigators can be at any stage of their career. Additionally, **population-based studies that address health equity** may propose up to a maximum of 5 years and \$400,000 per year (direct costs), plus 20% allowable indirect costs (see Priority Area focus on Health Equity and Research Scholar Grant Instructions).

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

MENTORED TRAINING AND CAREER DEVELOPMENT GRANTS

Postdoctoral Fellowships—Support for researchers who have received a doctoral degree to provide training leading to an independent career in cancer research. Awards may be for 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 to attend the ACS Postdoctoral Fellows Symposium, if offered that year, or travel to a domestic scientific meeting

Mentored Research Scholar Grants—Provides support for mentored research and training to full-time junior faculty, typically within the initial four years of their first independent appointment. The goal is for these beginning investigators to become independent researchers as

either clinician scientists or cancer control and prevention researchers. Awards are for up to five years and for up to \$135,000 per year (direct costs), plus 8% allowable indirect costs. A maximum of \$10,000 per year for the mentor(s) (regardless of the number of mentors) is included in the \$135,000.

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

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

PREDOCTORAL TRAINING

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

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

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

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

AMERICAN CANCER SOCIETY PROFESSOR AWARDS

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

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

INTERNATIONAL PROGRAMS

Audrey Meyer Mars International Fellowships in Clinical Oncology—Support for one year of advanced training in clinical oncology at participating US cancer centers to qualified physicians and surgeons from other countries, particularly countries where advanced training is not readily available. This program is limited to non-US citizens and provides up to \$40,000 annually. Annual application deadline is February 1.

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

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 in rates of incidence, prevalence, mortality and related adverse health conditions in subgroups of the US population. If application of 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 by establishing inclusive health and social systems whereby all people are treated equitably creates conditions for improving health outcomes.

The American Cancer Society (ACS) has a longstanding history of advocacy, education, community outreach and research in the area of cancer disparities and continues to recognize the importance of research in the area. As highlighted in reports by the Agency for Healthcare Research and Quality and the Institute of Medicine, inequitable differences or health disparities are linked to various determinants of health. The determinants of health are interrelated risk factors that extend across the life span to impact health (Braveman, 2014). Environmental conditions—the conditions in which people are born, live, play, thrive, work and worship—and the available systems supporting health comprise the social determinants of health. Integral to these influences are the economic, political and social policies that exist in and shape communities. Besides sociopolitical influences, biology, genetics/genomics and individual behaviors are also determinants of health. Inequity and health disparities may be further

characterized by 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 US 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 and health disparities as a priority. Within the Cancer Control and Prevention Research Program of the Department, grant applications in psychosocial and behavioral research and in health policy and health services research focused on achieving health equity and eliminating health disparities are welcome from principal investigators at any career stage. This expanded eligibility is unique to the Priority Area Targeting Health Equity and Health Disparities in Cancer Prevention and Control. Applicants must explicitly specify the following within the application: (1) relevance to cancer generally and cancer disparities specifically; (2) how findings from the proposed research will substantially improve equity in access to cancer prevention, early detection, diagnosis, and/or treatment services; and (3) 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, Mentored Research Scholar Grant, Research Scholar Grant, or Clinical Research Professor. Annual deadlines: April 1 and October 15.

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>

REQUESTS FOR APPLICATIONS (RFAs)

Pilot and Exploratory Projects in Palliative Care of Cancer Patients and their Families — Supports investigators performing pilot and exploratory research studies that test interventions, develop research methodologies, and explore novel areas of research in palliative care of cancer patients and their families. Applications will be accepted via the Pilot and Exploratory Grants Mechanism. The maximum award is for 2 years and up to \$60,000 per year (direct costs) plus 20% indirect costs Annual Deadlines: April 1 and October 15

Pilot and Exploratory Studies Using Community-Based Participatory Research (CBPR) to Achieve Cancer Health Equity-This RFA supports the funding of pilot studies using community-based participatory research (CBPR) as a means to achieve cancer health equity. It is offered in collaboration with the American Cancer Society (ACS) Midwest Division to support researchers in that geographic region. An investigator may be at any career stage, but must be a resident of the Midwest Division of the American Cancer Society (Iowa, Minnesota, South Dakota and Wisconsin). Applications will be accepted via the Pilot and Exploratory Grants Mechanism. The maximum award is for two years and up to \$50,000 per year (including indirect costs.) Annual Deadlines: April 1 and October 15

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— This RFA is a call for research that evaluates the impact of the many changes now occurring in the health care system with a particular focus on cancer prevention, control, and treatment. Efforts focusing on improving access to care may also impact inequities that contribute to 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 to be funded by this RFA should focus 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. Award length and budget limits vary; please see the Research Scholar Grant policies and instructions for a detailed description of this RFA. Annual Deadlines: April 1 and October 15.

GRANT PROGRAMS

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

This program provides grants in support of nurses, physicians and social workers to pursue training in cancer prevention and control practice. The program’s goal is to accelerate the wide application of research findings in cancer prevention and control by increasing the number of nursing and social work clinicians, and researchers and physicians with expertise and career commitment to cancer control.

MOLECULAR GENETICS & BIOCHEMISTRY OF CANCER – Michael Melner, PhD,
Program Director

This program focuses on genes involved in cancer and how alterations in those genes (mutations, deletions, and amplifications) play roles 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 the disease. The program highlights new targets for prevention, detection, and treatment of cancer.

CANCER CELL BIOLOGY AND METASTASIS – Charles Saxe, PhD, Program Director

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

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

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

CLINICAL CANCER RESEARCH AND IMMUNOLOGY – **Open**

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

CANCER CONTROL AND PREVENTION RESEARCH –Elvan C. Daniels, MD, MPH,
Program Director

The program focuses on the study of behaviors (of individuals, health care professionals, or health care systems) or interventions in changing these behaviors or systems which result in a reduction in cancer risk, improved early detection, better informed decision-making, or improvements in the quality of life of patients and families. Special emphasis is placed on research focused on achieving health equity in disadvantaged groups.

2. AUTHORITY FOR MAKING GRANTS

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

3. SOURCE OF FUNDS

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

4. WHO MAY APPLY

Applicants for Mentored Research Scholar Grants and Postdoctoral Fellowships must at the time of application be United States citizens or permanent residents of the United States. For Research Scholar Grants, Institutional Research Grants, Physician Training Awards in Cancer Prevention, and ACS Professors, there are no citizenship requirements.

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 that are in response to RFAs and for PIs of Institutional Research Grants.

5. COLLABORATIONS WITH ACS INTRAMURAL SCIENTISTS (if needed)

- 1) Extramural scientists are allowed to submit grant applications for funding which include collaborations with ACS Intramural Research scientists
- 2) In most cases, the use of ACS research resources will require that at least one ACS intramural scientist is 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 established by ACS Intramural Research.
- 3) Intramural scientists and their staff may participate in grants and contracts in a number of ways, including:
 - Serving as unpaid consultants, collaborator, co-investigator or mentor. 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 project grant (e.g. RSG).
 - Developing/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) The intramural scientist or extramural scientist may have access to reagents, probes, laboratory equipment or access to data and 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, collaborating intramural scientist should review and approve the appropriate sections.
- 7) ACS intramural scientist participation must comply with the policies and procedures related to conflict of interest, non-disclosure and disclosure regulations and conflict of interest.

8) ACS intramural scientists must file annual and final research reports related to their activities associate with any grant or contract awarded through the Extramural Grants Department.

¹Adapted from document NIH Policy 54815 Implementation of Cooperative Agreement, and “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>]

6. ELIGIBLE INSTITUTIONS AND INSTITUTIONAL RESPONSIBILITIES

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

- A current letter from the Internal Revenue Service conferring 501(c)(3) status,
- Documentation of an active cancer research program

Unsolicited grant applications will not be accepted from, nor will grants be made for, the support of research conducted at for-profit institutions, federal government agencies (including the National Laboratories), or organizations supported entirely by the federal government (with the exception of postdoctoral fellowship applications) or organizations, such as Foundations operated by, and for the benefit of, Veteran Affairs Medical Centers, whose primary beneficiaries are federal government entities. Applications may be submitted by qualified academic institutions on behalf of Veteran Affairs Medical Centers, provided that a Dean’s Committee Memorandum of Affiliation is in effect between the two institutions.

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

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

The institution is responsible for verifying that all documentation related to the application and/or grant, including all representations made by any named researcher (e.g. position or title), is correct. Further, it is the responsibility of the institution to verify that the applicant is either a US citizen or permanent resident with a Resident Alien Card or “Green Card,” where applicable.

If the award does not require US citizenship or permanent residency as an eligibility requirement, the institution is responsible for documenting that the applicant is legally eligible to work in the US for the duration of the award.

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 conflict, or misconduct, or any change in a named researcher's employment status with the institution, including administrative leave, which may occur during the term of any award that is pertinent related to the work described in the grant application. Failure to abide by the terms above, or any other ACS policies and procedures in connection with the application and/or grant, may result in ACS suspending grant funding, or canceling the grant, to be decided by ACS in its sole discretion.

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

7. TOBACCO-INDUSTRY FUNDING POLICY

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

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

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

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

8. PEER REVIEW OF APPLICATIONS

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

Depending on the grant applied for (see specific sections), the committees evaluate applications based on some or all of the following criteria: (a) the scientific merit, originality, and feasibility of the application; (b) the qualifications, experience and productivity of the applicant, and the members of the investigative team; (c) the facilities and resources available; and (d) the promise of the research or training as related to the control of cancer or to the benefit to be gained by persons with cancer. At the Peer Review Committee meeting, the most competitive applications are discussed and a priority score is voted. Written evaluations of each application are provided to the Council for Extramural Grants (the Council). The Council is a multidisciplinary panel of senior scientists, many having previously served on a Peer Review Committee, up to three stakeholders, and the Chair of the Society’s Research and Medical Affairs Committee serving as an ex officio, non-voting member. After considering the relative merit of the applications, the amount of available funds and the Society’s objectives, the Council establishes the pay line to determine 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 ACS staff or serve concurrently on the Board of Directors of the American Cancer Society.

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

9. APPLICATION DEADLINES

Applications for grants and awards must be submitted as paper and electronic copies via proposalCENTRAL. Access is available using links provided in the American Cancer Society web site www.cancer.org (see *Instructions*). The electronic applications must be submitted at the proposalCENTRAL website by close of business (5:00 PM EST) on the specified deadline date. For the convenience of the applicant, paper copies are due one day after submission of the electronic copy. **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 staff for administrative purposes or when requested by the reviewers. The schedule for application receipt and review is provided in the following table.

DEADLINE, REVIEW, NOTIFICATION, AND ACTIVATION SCHEDULE

GRANTS	Deadline for Receipt of Electronic Applications*	Peer Review Meeting	Preliminary Notification	Council Meeting	Grantee Notification	Activation
Research Scholar Grant	April 1 October 15	June January	August March	Sept. March	October April	January 1 July 1
Mentored Research Scholar Grant	April 1 October 15	June January	August March	Sept. March	October April	January 1 July 1
Postdoctoral Fellowship	April 1 October 15	June January	August March	Sept. March	October April	January 1 July 1
Pilot and Exploratory Projects	April 1 October 15	June January	August March	Sept. March	October April	January 1 July 1
Institutional Research Grant	April 1	June	August	Sept.	October	January 1
Physician Training Award in Cancer Prevention	April 1	June	August	Sept.	October	January 1
Research Professor Award	LOI Deadline: February 1	June	NA	Sept.	October	January 1
	Application Deadline: April 1					
Doctoral Training Grant in Oncology Social Work	October 15	January	March	March	April	July 1
Clinical Research Professor Award	LOI Deadline: August 1	January	NA	March	April	July 1
	Application Deadline: October 15					
Master's Training Grant in Clinical Oncology Social Work	October 15	January	March	March	April	July 1
Cancer Control Career Development Award	October 15	January	March	March	April	July 1
Doctoral Degree Scholarship in Cancer Nursing	October 15	January	March	March	April	July 1

Graduate Scholarship in Cancer Nursing Practice	February 1	March	N/A	April	May	July 1
Audrey Meyer Mars International Fellowships in Clinical Oncology	February 1	N/A	N/A	March	April	July 1

***Paper copies are due one business day following the deadline for electronic copies**

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 and telephone number of their Scientific Program Director. This email will be sent to the address in the Professional Profile supplied at the time of submission in proposalCENTRAL. It is important that the address listed in the Professional Profile is a viable mailing address as it will be used to notify you throughout the review and award process.

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

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

11. GRANT MANAGEMENT AND PAYMENTS

New grantees will receive a packet of information which includes instructions for activation of the award. The activation form as well as other important information about the grant can 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 requires that all payments are made to the sponsoring institution and are mailed to the address indicated on the grant activation form. Acknowledgment of payment by the

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

Personnel compensated in whole or in part with funds from the American Cancer Society are not considered employees of the Society. Institutions are responsible for issuing the appropriate IRS tax filings for all individuals receiving compensation from American Cancer Society grants and are responsible for withholding and paying all required federal, state, and local payroll taxes with regard to such compensation. 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, and Postdoctoral Fellowships. For all other grants, see the appropriate "Required Progress Reports" sections. Annual and final reports represent a critical part of responsible stewardship of the donated dollars. We greatly appreciate your efforts to assist us in fulfilling this important commitment to our donors.

- 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, and final reports are due within sixty days after the grant has terminated. To access the necessary forms for annual and final progress reports, please go to <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 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. Reports are to be submitted in a timely manner. If this is not possible, a written request to extend the reporting deadline must be made. Otherwise, noncompliance may result in the withholding of payment on all grants in effect at the recipient institution until reports are received.
- 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 RESEARCH COMMUNICATIONS

Publications resulting from research or training activities supported by the American Cancer Society must contain the following acknowledgment: "Supported by (insert name of grant and number) from the American Cancer Society." In the event that there are multiple sources of support, the acknowledgment should read "Supported in part by (insert 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 by the institution in all public communication of work resulting from this grant, including scientific abstracts (where permitted), posters at scientific meetings, press releases or other media communications, and Internet-based communications.

Although there is no formal approval process for publications by Society grantees, **it is helpful if investigators notify their Program Directors when manuscripts have been accepted for future publication.** This will allow ample time to consider and coordinate any additional public or Society-wide notifications. If your institution decides to send out a **press release** involving any of your Society-supported research, please notify your local ACS Division office (phone number on your award letter) or your Program Director in advance.

ACS grants to you a limited, revocable, non-transferable license to use the ACS logo (as shown below) in connection with your funded work. We encourage you to use the following ACS logo on any scientific poster, in a Power Point presentation, or 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 to ACS upon our request.

Permission to use the logo is limited to the uses outlined in the above paragraph. Any other use must be evaluated and approved in writing by the ACS prior to any such use. Please contact your Program Director regarding any other proposed use of the logo.



14. FINANCIAL RECORDS AND REPORTS

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

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

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

15. EXPENDITURES

American Cancer Society *research* grants are not designed to cover the total cost of the research proposed nor the investigator's entire compensation. The grantee's institution is expected to provide the required physical facilities and administrative services normally available 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, Cancer Control Career Development Awards and Physician Training Awards in Cancer Prevention).

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

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

However, Society research and training grant funds can be used for computer purchases that are for research and training purposes, and 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 extensions thereof is for the use of the principal investigator and collaborators. Title of such equipment shall be vested in the institution at which the principal investigator is conducting the research. In the event the American Cancer Society authorizes the transfer of a grant to another institution, equipment necessary for continuation of the research project purchased with the grant funds may be transferred to the new institution. Title to such equipment shall be vested in the new institution.

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 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. EXTENSION OF TERM OF GRANT/TRANSFERS/LEAVE OF ABSENCE

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

Requests for a leave of absence will be handled on a case-by-case basis. In general, the funds to be carried over into the no cost period should not exceed an amount equivalent to one year of support (direct plus indirect). Please contact the Program office prior to commencing leave.

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

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

19. CANCELLATION OF GRANT

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

The American Cancer Society may cancel a grant in 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 the Postdoctoral Fellowship is cancelled prior to its end date, payments of the fellowship allowance will be prorated on a monthly basis. **The Society cannot assume responsibility for expenditures in excess of the prorated amount.**

Please note that if the award is to be canceled after 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.

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

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:

A. 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. Research 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. <http://iom.edu/Reports/2005/From-Cancer-Patient-to-Cancer-Survivor-Lost-in-Transition.aspx>
- American Academy of Pain Management, Index of Resources. <http://www.aapainmanage.org/resources/index.html>
- National Cancer Survivorship Resource Center. <http://www.cancer.org/treatment/survivorshipduringandaftertreatment/nationalcancersurvivorshipresourcecenter/index>
- National Hospice and Palliative Care Organization, Index of Resources. <http://www.nhpco.org/resources>

B. Pilot and Exploratory Studies Using Community-Based Participatory Research (CBPR) to Achieve Cancer Health Equity

Overview: CBPR is a collaborative research approach that is action-oriented and community-driven. Community/research partnerships are valuable because of their potential for developing models and approaches for building effective communication, trust, capacity, shared decision making and ultimately increasing community participation in the research process (from conceptualization to implementation, analysis and dissemination). This approach recognizes the unique strengths of each partner.

CBPR Nine Guiding Principles (Israel et al., 1998)

1. Recognizes community as a unit of identity.
2. Builds on strengths and resources within the community.
3. Facilitates a collaborative, equitable partnership in all phases of research, involving an empowering and power-sharing process that attends to social inequalities.
4. Fosters co-learning and capacity building among all partners.
5. Integrates and achieves a balance between knowledge generation and intervention for the mutual benefit of all partners.
6. Focuses on the local relevance of public health problems and on ecological perspectives that attend to the multiple determinants of health.
7. Involves systems development using a cyclical and iterative process.
8. Disseminates results to all partners and involves them in the wider dissemination of results.
9. Involves a long-term process and commitment to sustainability.

Recommended CBPR Resources:

a. Organizations

- Local Practice-Based Research Networks (PBRNs) registered with the Agency for Healthcare Research and Quality
- Local institutions with Clinical and Translational Science Awards (CTSAs)
- Local NCI Community Cancer Centers
- Local NCI-Designated Comprehensive Cancer Centers
- Local institutions that are part of the NCI's National Outreach Network (NON), which provides outreach and education to underrepresented and at-risk communities.
- Local members of the Community Clinical Oncology Program (CCOP), which connects academic centers with community physicians
- Schools of public health and medicine at local institutions

b. Online Resources

Achieving the Promise of Authentic Community-Higher Education Partnerships: Community Partners Speak Out! Seattle, WA: Community-Campus Partnerships for Health, 2007.

http://depts.washington.edu/ccph/pdf_files/CPSReport_final1.15.08.pdf

AHRQ Activities Using Community-Based Participatory Research to Address Health Care Disparities.

<http://www.ahrq.gov/research/findings/factsheets/primary/cbprbrief/index.html>

CBPR Toolkit, AAPCHO, National Association of Community Health Centers (NACHC).

http://www.aapcho.org/resources_db/cbpr-toolkit/

CTSA Community Engagement Key Function Committee Task Force on the Principles of Community Engagement (Second Edition).

http://www.atsdr.cdc.gov/communityengagement/pdf/PCE_Report_508_FINAL.pdf

NIH Office of Behavioral and Social Sciences Research, Community-Based Participatory Research.

http://obssr.od.nih.gov/scientific_areas/methodology/community_based_participatory_research/

21. ELIGIBILITY FOR PILOT AND EXPLORATORY PROJECTS

Eligibility for this mechanism varies depending on the particular RFA.

A. PILOT AND EXPLORATORY Projects in Palliative Care of Cancer Patients and Their Families

1. Applications may be submitted by not-for-profit institutions located within the United States, its territories and the Commonwealth of Puerto Rico.
2. Applicants must be United States citizens, non-citizen nationals or permanent residents of the United States.

3. 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.
4. 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.

B. PILOT AND EXPLORATORY STUDIES USING CBPR TO ACHIEVE CANCER HEALTH EQUITY

1. Applicants must work at not-for-profit institutions located within Iowa, Minnesota, South Dakota, or Wisconsin.
2. Applicants must be United States citizens, non-citizen nationals or permanent residents of the United States.
3. 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.
4. 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 varies depending on the RFA.

- **PILOT AND EXPLORATORY STUDIES IN PALLIATIVE CARE:** 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.
- **PILOT STUDIES USING CBPR TO ACHIEVE CANCER HEALTH EQUITY:** Awards from either funding source may not exceed a period of two years duration with a maximum budget of \$50,000 per year (**including indirect costs**). Salary support for the Principal Investigator may not exceed 20% of the funded project's direct cost.

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 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? What is unique regarding the approach to address health equity in the context of one or more of the determinants of health? How has innovation been enhanced by community engagement?

- **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?

For Pilot Studies Using CBPR to Achieve Cancer Health Equity:

Is there evidence of value-added team members as a result of this academic-community partnership? Is it apparent that community partner(s) were sufficiently involved throughout the research planning and will be involved in tangible ways in the implementation process? Is there convincing evidence of previous collaboration of this academic-community partnership? If the partnership is new, how will the collective assets of both partners facilitate the success of this study and provide the foundation for future collaboration?

- **Approach**

Is the community and study population well-defined? Is the study design appropriate to address the specific aims? Are the overall strategy, methodology, and analyses well-

reasoned and appropriate to accomplish the specific aims of the project? Do community partners have meaningful involvement in study implementation? Are the conceptual or clinical framework, design, methods, and analyses adequately developed, well integrated, well-reasoned, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics? 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 plans 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?

For Pilot Studies Using CBPR to Reduce Cancer Disparities:

How will this study mutually benefit partners? Are there meaningful plans for sustainability and future collaboration with sufficient clarity? This may include enhancing the capacity of the community partner(s), e.g., grant seeking and writing activities, enhancing communities' ability to access information, advocacy skills.

- **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?

24. KEY DATES

Full Proposal Deadline	April 1, 2015
Applications Reviewed in Committee	June 2015
Preliminary Notification of Outcome	August 2015
Applications Reviewed in Council	September 2015
Notification of Awards	October 2015
Award Start Date	January 1, 2016

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 National 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 National 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, ppg. 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. What is considered a COI – a recent publication, grant collaboration, trained together
- 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 The above definitions are outlined in the Federal Guidelines [Federal Register, Vol.65, No.235, ppg: 76260-76264]

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 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), flashdrives, 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 National Vice President for Extramural Research at ACS. The National 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 National Vice President for Extramural Research at ACS. The National 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, National 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 National Vice President for Extramural Research who will determine if an investigation of that allegation is warranted. The National 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 National 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 National Vice President for Extramural Research who will determine if an investigation of that allegation is warranted. The National 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 National Vice President for Extramural Research of the allegation, and provide all relevant information regarding the allegation. It is the National Vice President’s responsibility to evaluate the likelihood of scientific misconduct; and, if warranted, it is the National Vice President’s responsibility to contact the appropriate institutional office at the applicant’s institution regarding the allegation. The National 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 National 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 National 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 National 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 National 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 National Vice

President for Extramural Research of the allegation, and provide all relevant information regarding the allegation. It is the National Vice President's responsibility to evaluate the likelihood of scientific misconduct; and, if warranted, it is the National Vice President for Extramural Research's responsibility to contact the appropriate institutional office at the applicant's institution regarding the allegation. The National 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 National 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 National 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 National 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 National 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 National Vice President for Extramural Research of the allegation, and provide all relevant information regarding the allegation. It is the National Vice President for Extramural Research's responsibility to evaluate the likelihood of reviewer conflict of interest or misconduct; and, if warranted, it is the National 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 National 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 National 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 National 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 National 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 is pleased to announce our continued association with Altum proposalCENTRAL by subscribing to the **Post Award Management System**. The system is designed to collect grant post award information from grantees. Grantees are asked to keep their proposalCENTRAL profile current for the duration of the grant.

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

All awardees of an ACS grant will need to upload deliverables, and then send an email (correspondence) to the Program Director/Program Coordinator informing the program office of the submitted deliverables. The first deliverable we will be collecting through the **Post Award Management System** is the “Activation Form.” For the Activation Form only, please also email Mary LeMahieu at mary.lemahieu@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.altum.com>
- **PI must enter their ProposalCentral username and password in “Applicant Login” to access their award detail information**
- Click on the Awarded link or all Proposal link
- In the Status column, click on the Award Details link
- On the Award Details screen, click on the Deliverables link at the bottom of the screen

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

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

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

Send Email (Correspondence) to an ACS Administrator

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

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

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

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

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

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

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

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

- Click "Browse" to upload their document
- Click "Save"

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

By phone: 1-800-875-2562 toll free

By email: pcsupport@altum.com

PILOT AND EXPLORATORY PROJECT

INSTRUCTIONS

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A. GENERAL INFORMATION

1. ACCESSING THE ACS GRANT APPLICATION SYSTEM

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

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

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

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

2. FORMATTING THE APPLICATION

Applicants must adhere to the following instructions.

- Insert your name in the header for each section of the application
- All application documents should be single-sided.
- **Type size:** Use 12 point Times New Roman or 11-point Arial as the minimum font size for the text of the application. A 10-point Times New Roman or 9-point Arial font type may be used for figures, legends, and tables.
- **Single-spaced text** is acceptable, and space between paragraphs is recommended.
- **Margins:** The margins of your text should be at least 0.5 inches all around, unless a form with different margins is supplied in the Application Templates.
- **Page numbering:**
 - Cover Pages-** The first few pages of the application form are considered cover pages and are not numbered. The cover pages include the Signature Page, Contact Page, General Audience Summary and Structure Technical Abstract (if applicable).
 - Proposal Sections-** The proposal sections are listed in the Table of Contents and must be numbered in the upper right hand corner. Each section should be numbered independently.
- **Appendix:** The appendix is now part of the electronic application.

3. RESUBMISSION OF AN APPLICATION

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

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

4. CHANGES TO THE APPLICATION

Withdrawal of application: Please advise the Society promptly, in writing (or email), should you decide to withdraw your application for any reason. Your letter (or email) to the Program Director identified in the application acknowledgment letter should include your name, the application number, and the reason for withdrawal. If you are withdrawing because you have accepted funding from another organization, please let us know who will be funding your work.

Change of address: Notify the Society in writing (email) of any changes of address, email or phone number, following the submission of an application. Include your name and the application number. We also recommend that you update your information in proposalCENTRAL.

Change of institution: If you are an applicant for an ACS grant and change your institution, contact the Program Director identified in the acknowledgment email, who will determine whether your application can be reviewed.

5. EXPLANATION OF REQUIRED INFORMATION

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

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

Principal Investigator/Applicant Information: Some (or all) of the required information will have been automatically filled in from your profile. The information was provided when you initially registered with proposalCENTRAL and completed the Professional Profile. If any of this

information is not current at the time of submission, you will need to update the Professional Profile before finalizing this section and submitting the final version of your application. Pay particular attention to you contact information as all notifications to you will be sent using this information. Please keep contact information up to date.

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

Citizenship Status: An appropriate selection must be made in the Professional Profile. Indicate your current citizenship status. You must provide your country of citizenship.

Justification of Eligibility: Applicants for American Cancer Society Extramural Grants must satisfy the eligibility requirements defined from each application type. Please indicate the month and year when your last degree was conferred, as well as the month and year of your first independent faculty (or equivalent) position where requested. If your case was evaluated by the American Cancer Society eligibility committee, include a copy of the letter the appendix, list it in the table of contents, and refer to it in the justification space provided.

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

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

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

Department Chair: Indicate name, department, and email address of the department chair. Department chairs should sign the front page to affirm the title of investigator and the committed resources.

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

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

6. GENERAL AUDIENCE SUMMARY

The general audience summary is a very important part of the application and is intended to provide a clear overview of the proposed research to people who are *not* trained in the sciences

but who are interested in cancer research. These include stakeholders, ACS staff members, potential donors and the general public. **Stakeholders** are individuals without formal scientific or medical training who have a strong personal interest in the prevention and control of cancer. They are included as full voting members of all peer review panels. The Stakeholder evaluation of the general audience summary becomes an important part of the overall review of the application by the peer review committee since their primary focus is on how the proposed work will be of value to cancer patients and their families.

ACS staff members who work with major donors also use these summaries to identify projects appropriate to the interests of donors who wish to support specific areas of cancer research. Furthermore, summaries of all grants made by the Society are made available to the **general public**. ACS staff members with responsibility for communicating ACS research to local media may also use the summaries to describe the research funded in a particular region of the country.

The general audience summary must *not* duplicate the structured technical abstract. It should be written in a way that makes the project easily understood by the audience described above without scientific jargon. **See the Samples of General Audience Summaries in the Appendix for examples of a properly constructed summary.** This summary should describe the background to the research, the questions to be asked, and the information to be obtained. The use of symbols and Greek characters should be avoided for the general audience; if they must be used, they have to be spelled out since they will not appear as characters in the text.

*This form is limited to 3,000 characters, including spaces and will truncate at that point. Characters in excess of the limit are not transmitted with the application resulting in an incomplete summary. **Failure to submit this correctly may result in the disqualification of your application.***

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

7. STRUCTURED TECHNICAL ABSTRACT

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

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

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

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

- **Cancer relevance:** Provide a brief statement explaining the potential relevance of the proposed work to cancer and the American Cancer Society's mission of eliminating cancer as a major health problem.

*This form is limited to 3,000 characters, including spaces and will truncate at that point. Characters in excess of the limit are not transmitted with the application resulting in an incomplete summary. Please submit a complete Structured Technical Abstract within the character limit. **Failure to submit this correctly may result in the disqualification of your application.***

8. PROJECT CODING

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

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

The information requested is not part of the application used by the Peer Review Committee for scientific review, and should not be submitted with your paper copy. However, the information is important and assists the Society in communication to the public about its portfolio of applications and grants.

9. ASSURANCES AND CERTIFICATION

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

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

All research supported by the American Cancer Society (including subcontracted activities) involving vertebrate animals must be conducted at performance sites which are covered under an approved Animal Welfare Assurance **It is the responsibility of the institution to immediately report to ACS any action including recertification or loss of IACUC approval which may**

occur during the term of any award that is pertinent to the work described in the grant application.

Human subjects. All proposed research projects involving human subjects must be approved by the appropriate Institutional Review Board (IRB).

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

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

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

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

10. PI DATA SHEET

Submit this section electronically only.

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

11. APPLICATION SUBMISSION AND REQUIRED SIGNATURES

Applications must be submitted in two formats: an electronic version and 2 paper copies.

A. SUBMISSION OF ELECTRONIC APPLICATION

- **All application attachments must be uploaded as .pdf documents.** See proposalCENTRAL FAQ or contact support at 1-800-875-2562 if you need assistance.
- **Validate** the application on proposalCENTRAL. This is an essential step. An application that has not been validated cannot be submitted.
- Print application via proposalCENTRAL. To do so, choose “Print” on the menu and select “Print Signature Pages and Attached PDF Files”. **Do not print cover pages for an application that has not been validated.**
- If you wish, print and retain for your files the paper copies of the Demographic and Research Promotion Information and the Project Coding sections. Do not submit these sections in the paper copy of your application.
- Get all signatures on the paper copy before submitting. Please note, the signed copy of the front page is NOT uploaded in the electronic version; it is to be submitted with the paper copies.
- If any modifications were made during the signature process, make certain that all sections of the electronic version are revised to match the paper copy that is being submitted.
- If you have technical questions regarding the electronic application process, feel free to contact Altum at pcsupport@altum.com or 1-800-875-2562.
- Submitting electronic version of application should be done after your institution has prepared the application for mailing. You have until 5:00 PM Eastern time on the deadline date to complete the electronic submission. Note that the appendix materials are now submitted electronically. Paper copies will no longer be provided to reviewers so any appendix materials must be uploaded to proposalCENTRAL to be considered during the review process.

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

B. ASSEMBLY AND SUBMISSION OF PAPER COPIES

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

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

See program specific instructions for additional required signatures.

The application with the signature page plus one copy must be received by the American Cancer Society Corporate Center no later than 5:00 PM Eastern time on the next business day following the deadline date for the electronic submission.

The paper copies must be assembled as described below. To reduce the chance of losing an application, we urge institutions to mail only one application and its copy per package. If more

than one application is included in a package, provide a bright-colored cover sheet listing the applications enclosed and stating in ½ inch or larger lettering "MULTIPLE APPLICATIONS ENCLOSED." Both sets of the application (application with signatures plus the copy) must arrive in the same package.

The original and the copy of the application should be held together with a rubber band or binder clips. Please **do not** staple. Send the complete application package to:

**The American Cancer Society
Extramural Grants Department
250 Williams Street NW, 6th Floor
Atlanta, GA 30303
404-329-7558**

B. PREPARING THE APPLICATION

1. COVER PAGES

Program Eligibility Information. Most of the information that is collected online at proposalCENTRAL appears on the cover pages. This includes program eligibility information: (1) Last degree conferred and (2) Independent position date. This information *is required* to determine eligibility for this RFA. If you have received a letter from the American Cancer Society regarding your eligibility, *manually* indicate this on the cover page in the Program Eligibility Information section and attach the letter in the Appendices.

2. APPLICATION TEMPLATES

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

3. TABLE OF CONTENTS (PAGE 1.1)

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

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 below.

A. Personal Statement

Briefly describe why you are well-suited for your role in the project described in this application. The relevant factors may include aspects of your training; your previous experimental work on this specific topic or related topics; your technical expertise; your collaborators or scientific environment; and your past performance in this or related fields (you may mention specific contributions to science that are not included in Section C). Also, you may identify up to four peer reviewed publications that specifically highlight your experience and qualifications for this project. If you wish to explain impediments to your past productivity, you may include a description of factors such as family care responsibilities, illness, disability, and active duty military service.

B. Positions and Honors

List in chronological order previous positions, concluding with the present position. List any honors. Include present membership on any Federal Government public advisory committee.

C. Contributions to Science

Briefly describe up to five of your most significant contributions to science. For each contribution, indicate the historical background that frames the scientific problem; the central finding(s); the influence of the finding(s) on the progress of science or the application of those finding(s) to health or technology; and your specific role in the described work. For each of these contributions, reference up to four peer-reviewed publications that are relevant to that contribution. The description of each contribution should be no longer than one half page including figures and citations. Please also provide a URL to a full list of your published work as found in a publicly available digital database such as PubMed or My Bibliography, which are maintained by the US National Library of Medicine.

D. Research Support

List both selected ongoing and completed research projects for the past three years (Federal or non-Federally-supported). *Begin with the projects that are most relevant to the research proposed in the application.* Briefly indicate the overall goals of the projects and responsibilities of the key person identified on the Biographical Sketch. Do not include number of person months or direct costs.

5. REPLY TO PREVIOUS REVIEW (resubmissions only) (PAGE 3.1)

IF THE APPLICATION IS A NEW SUBMISSION upload the provided template with “Not Applicable” in the body. For resubmissions this section should clearly and briefly address the points raised in the previous reviews and direct the reader to the specific sections where text revisions have been made. Text changed in response to reviewers’ comments should be identifiable in the revised application (e.g. bold type, line in the margin underlining, etc). 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 12 pages. This page limit does not include Experimental Details (G), Environment (H), or the References (I). Proposals should be realistic in terms of work to be accomplished in the period of time for which support is requested. Although it is permissible to submit applications on an "either/or" basis with other agencies, proposals should be adjusted to fit the Society's term and budget constraints. Failure to conform to the guidelines on type size, page length, or project scope may result in the application being returned to the investigator 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 cancer prevention, diagnosis, treatment, survivorship, or quality of life in the community.
- B. 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 and should address critical gaps in knowledge to reduce cancer disparities. Additionally, the theoretical model(s) that underpins the research approach and forms the basis of your conceptual framework should be summarized here. If aims are realized, how will the results of this study impact cancer disparities, social change and/or policy leveraging the academic-community partnership?
- C. Statement of Cancer Relevance (max 250 words).** What is the cancer relevance and importance to the targeted audience, community and/or on the field of cancer research? This section of the application is important to the Stakeholders (non-scientific members) on the Peer Review Committees and to a number of general audiences, including donors. The use of technical terminology or scientific jargon should therefore be avoided. Describe the short-term and long-term contributions the project is designed to make to the prevention and control of cancer. Outline the expected contribution of the study to controlling the overall cancer burden. This description might include: an estimate of the potential patient target population; anticipated effects on morbidity and/or mortality; possible impact on quality of life; and the extent to which the findings may be applicable beyond the specific aspect of cancer to be investigated. This section should not exceed 250 words.
- D. Innovation.** Provide a rationale for why this proposed research is novel/innovative in ways that uniquely address health equity in the context of one or more of the determinants of health in the targeted community. Describe how the research question was developed and how the community was/will be involved in contributing to the design and implementation of the study to address potential barriers and the dissemination of results.

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

E. Preliminary Studies and Previous Experience. Provide results of research accomplished by you that are relevant to this proposal in a sufficiently comprehensive manner to indicate their significance. For community-based participatory research, describe the process for formulating the research question/project purpose and conceptualization of the research study methods among partners to include tangible important and relevant aspects that foster community engagement to collaboratively address the targeted area of health equity. Provide a succinct summary of the previous work of this academic-community partnership including specific accomplishments pertinent to the proposed scope of work. If the partnership is new, describe how the collective assets of both partners will facilitate the success of this study and provide the foundation for future collaboration.

Reprints or preprints may serve in lieu of a detailed report and should be included in the appendix. Reprints and preprints should be included in each appendix set. Note that the entire application is considered confidential, including reports of unpublished research.

F. Research Design and Methods. Describe your proposed methods and procedures in sufficient detail to permit evaluation by other scientists. A specific study design and a theory-driven implementation strategy integrated within a defined community and targeted setting (e.g., community-based organizations, faith-based organizations, federally qualified health centers, community physician offices, community/residential associations). Discuss potential difficulties and limitations of the methods and procedures, and provide alternative approaches. Order your priorities, and estimate the length of time that you believe will be required to complete each specific aim. Although the time estimated should not exceed the term for which support is requested, it is helpful to state how this project fits in with your long-term research goals.

This section should include:

- 1. Community and study population.** Concisely describe the targeted community in the context of the determinants of health contributing to the cancer disparity, the community setting, and the subset of community population targeted by the proposed research.
- 2. Research approach.** State the study design and describe implementation methods, the plan for data collection and analysis, limitations, the evaluation plan (for program projects or dissemination and implementation studies), the study timeline, and future plans.

G. Experimental Details (optional – not to exceed 3 pages). This optional section is available if the applicant believes a more in-depth description of the experimental design will provide additional significant information for the reviewer. It is not meant for procedural minutiae, but to indicate to reviewers the applicant's understanding of the specific approaches and

procedures proposed. The applicant may also use this space to provide a tentative timeline for completion of the project.

- H. Environment.** Describe briefly the space and equipment available for you to carry out the proposed research project. Investigators must have an institutional commitment of research facilities. The amount of committed space must be verified by the Department Chair (signature required on title cover of the application). This section is of major importance for applicants whose appointment is not in the tenure stream.

Pilot and Exploratory Studies Using CBPR to Achieve Cancer Health Equity

applications: Describe the study team and unique aspects of this academic–community partnership that make this collaboration well suited to carry-out the scope of work. Describe the academic-community partnership, how it was formed, the shared management for study implementation, how decisions will be made, and how communication will be maintained. Describe the community advisory board’s role and composition and how it will be involved in decision making. Provide a list of the collaborators and a description of present or planned contractual relationships.

CBPR applications: Plan for Sustainability of the Partnership

Describe strategies for enhancing the capacity of communities to maintain the evidence-based intervention beyond the project period. Strategies may include the inclusion of activities that will facilitate community engagement in future research and build skills to impact policy (e.g., grant seeking and writing activities, enhancing communities ability to access information, advocacy skills). Include details regarding how planned capacity building will facilitate sustainability of the partnership for future cancer research.

- I. References.** The list of references should correspond to the citations under headings A-D above. Each literature citation should include the names of all authors, title, book or journal, volume number, page numbers, and year of publication. There is no page limitation for the list of references and this section is not included in the 13-page limit (Sections A-F).

8. DETAILED BUDGET (PAGE 5.1)

- A. Personnel.** Names and positions of all personnel must be individually listed and the percentage of time to be devoted to the project by each person should be noted, even when salary is not requested. 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.)

List all collaborators (defined as individuals who will participate actively in the design and execution of the studies) and consultants (defined as individuals who will provide any

combination of advice, guidance, and reagents without “hands on” involvement in the project). Include letters of intent to collaborate or consult in the Appendix. Details of contractual arrangements with collaborators or consultants should be provided in the Justification of Budget section of the application.

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 – Defined as expendable property with a purchase cost per unit that is less than \$5,000 and/or that has a short service life (<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 or laptops 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, laptops 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 into major categories (glassware, chemicals, radioisotopes, survey materials, animals).

D. Travel. Travel funds are restricted for domestic travel only, although special consideration will be given for attendance at scientific meetings held in Canada.

PEP in Palliative Care applicants only: 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 expenditures allowed include: publication costs, 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 and provide a categorical breakdown of costs using duplicate copies of the grant application Budget and Justification of Budget pages. Subcontracts required to complete the research project may be with public or private institutions provided that they are not in violation of 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; and 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.

Pilot and Exploratory Studies Using CBPR to Achieve Cancer Health Equity applications: List the main community partner institution(s)/organization(s) for which consortium/contractual arrangements are planned.

Administrative pages: A Letter of Agreement pertaining to the subcontract should be included in the Appendix. Note: indirect costs for the subcontract budget may be claimed by either the primary or the secondary institution, but not both.

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 indirects, 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

Justify all items of permanent equipment costing over \$5,000 (see section 4.B above), the need for personnel, supplies, travel, and other miscellaneous items. If the budget includes a request for funds to be expended outside the United States, its territories, or the Commonwealth of Puerto Rico, this section should include an explanation of why such costs are essential for the successful conduct of the project, and why there are no alternatives.

Pilot and Exploratory Studies Using CBPR to Achieve Cancer Health Equity applications: List all consortiums/contractual arrangements. List the collaborators and describe present or planned contractual relationships.

10. BIOGRAPHICAL INFORMATION OF KEY PERSONNEL (PAGE 6.1)

Provide information for all key personnel involved in the project, including collaborators, even if no salary is requested. Do not include consultants or individuals that provide technical assistance. Give complete references for all peer reviewed publications. Begin each citation on a new line. If a partial listing is given, indicate total number of publications (including abstracts, non-peer reviewed articles and book chapters.) Do not exceed two pages per person for total biographical information. Make copies of the form if you have multiple key personnel. This is a required field. Therefore, if no Key Personnel are included, a blank form must be uploaded.

Pilot and Exploratory Studies Using CBPR to Achieve Cancer Health Equity

applications: The biosketch of the main community collaborator(s) should also include:

- a. **Education and training:** List all degrees (year conferred, institutions, field of study).
- b. **Personal statement:** Briefly describe why experiences and qualifications make you well suited for your role.
- c. **Positions and honors:** List in chronological order previous positions (concluding with present position), including employer, title, and duration of employment.
- d. **Publications or Presentations:** List publications and presentations (if any) that are pertinent to the proposed scope of work.

11. OTHER SUPPORT (PAGE 7.1)

It is the policy of the American Cancer Society **not** to fund projects that are supported all or in part by another agency; this means that projects are considered to overlap if there are **any** shared *Specific Aims or areas of budgetary overlap*. The Peer Review Committees will make the final decision regarding any questions of overlap. The only exceptions are: (a) funds provided by the institution as “start-up” support to develop a new laboratory or to gather pilot data, and (b) 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.

The following information is required for (1) the principal investigator and (2) all other professional persons listed on the budget page (including collaborators and subcontractors who will receive salary, but excluding consultants, postdoctoral fellows, technicians, and students). *Please provide this information for each person separately and in the following manner. Use continuation pages if necessary.*

1. **Current Support:** List all current awards including 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). For **each** award provide: (a) Source of funds-identify the agency, institute, foundation, or other organization that is providing the support. Include institutional, federal, public and private sources of support; (b) Grant number; (c) Title of project; (d) Dates of Approved/Proposed Project: Indicate the inclusive dates of the project as approved/proposed. For example, in the case of NIH support, provide the dates of the approved/proposed competitive segment; (e) Total Direct Costs; (f) Percent Effort/Person Months: For an active project, provide the level of actual effort in person months (even if

unpaid) for the current budget period. Person months should be classified as academic, calendar and/or summer; (g) Outline the goals of the project in a brief paragraph; and (h) *Clearly indicate whether there is any overlap between this grant and the proposed study.* If necessary, an explanatory letter may be included in the appendix to clarify the differences between the present application to the American Cancer Society and currently funded projects.

2. **Pending Support:** List all pending applications to other funding sources including 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). For **each** award provide: (a) Source of funds—identify the agency, institute, foundation, or other organization that is providing the support. Include institutional, federal, public and private sources of support; (b) Title of project; (c) Dates of Proposed Project: Indicate the inclusive dates of the project as approved/proposed. For example, in the case of NIH support, provide the dates of the approved/proposed competitive segment; (d) Total Direct Costs; (e) Percent Effort/Person Months. For a pending project, indicate the level of effort in person months as proposed for the initial budget period. In cases where an individual’s appointment is divided into academic and summer segments, indicate the proportion of each devoted to the project; (f) Outline the goals of the project in a brief paragraph. (g) *Clearly indicate whether there is any overlap between this grant and the proposed study.* If necessary, an explanatory letter may be included in the appendix to clarify the differences between the present application to the American Cancer Society and currently funded projects. In such cases, only one award can be accepted if both are approved for funding. The American Cancer Society does not negotiate partial funding of grants with overlapping specific aims.
3. **Institutional Support (The following information is required for the principal investigator only):** Include: (a) a description of any “start-up” funds provided by the Institution to the applicant; (b) details of the Institutional commitment to the support of the applicant’s salary; and (c) the current term of the applicant’s appointment. These details should be confirmed in the Statement of Institutional Support from the Department Chair included in Section 14, below. Please note that the award of “start-up” funds does not decrease the chances of obtaining support from the American Cancer Society; instead, such support is frequently considered by the Peer Review Committees as important evidence for institutional commitment to the research project.

For applicants whose appointment is not in the tenure stream, this section 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, information should be provided 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. Documentation should be included in the Statement of Institutional Support (Section 13, below) written by the Department Chair.

Please keep the Scientific Program Director current on the status of all pending applications.

12. LIST OF LETTERS OF SUPPORT FROM COLLABORATORS/CONSULTANTS (PAGE 8.1)

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

Pilot and Exploratory Studies Using CBPR to Achieve Cancer Health Equity applications:

Among the letters should be a letter of collaboration from the community partner(s) that documents their role, resources available (if any) to facilitate the study/project's success, and their commitment to the sustainability of the partnership. Also include a letter of support from the American Cancer Society's Midwest Division. To inquire about obtaining this letter please contact Karla Wysocki at karla.wysocki@cancer.org.

13. USE OF HUMAN OR ANIMAL SUBJECTS (PAGE 9.1)

Selection of study population: When conducting research on humans, provide the rationale for selection of your target population including the involvement of children, minorities, special vulnerable populations, such as, neonates, pregnant women, prisoners, institutionalized individuals, or others who may be considered vulnerable populations*. This should include research subject gender and the rationale for why certain populations may be excluded based on your research question and specific aims. Complete the planned enrollment form based on your proposed study sample size to estimate the total number of subjects by primary ethnicity and race, race/ethnicity subgroup (if applicable) and gender.

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

Research Specimens and Data: If the proposed research involves bio-specimens, provide a description of how the research material will be obtained from living subjects and what materials will be collected. Additionally, describe the specific non-biological data from human subjects and how it will be collected, managed and protected (e.g. demographic data elements), including who will have access to research data and what measures will be implemented 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.

***Note:** See the Department of Health and Human Services Office of Research Protection Subparts B-D for additional protections for vulnerable populations.

<http://www.hhs.gov/ohrp/policy/populations/index.html>

Vertebrate Animals.

Provide rationale for inclusion of live vertebrate animals according to the 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; and 3) justifications for, and appropriateness of, the numbers used for the experimental plan proposed.

Biohazards. Briefly describe whether materials or procedures proposed are potentially hazardous to research personnel, equipment, and/or the environment, and describe what protections will be used to mitigate any risk. The assessment related to biohazards should include potential biological or chemical hazards.

14. STATEMENT OF INSTITUTIONAL SUPPORT (PAGE 10.1)

A letter from the Department Chair (or equivalent) must be included in the application. This letter should clearly indicate the commitment of the institution to the support of the applicant and their research program. Details should include, but are not limited to, salary support, dedicated space for the research proposal, startup funds and the amount of protected time for clinical researchers. The letter should also describe the Department's long-term goals for the applicant's career.

15. 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)
- Evidence of Permanent Resident status (if applicable) Transcripts (if applicable)
- Recent reprints or preprints (optional)
- CDs/DVDs, mp4 Files (if applicable)
- 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 behavioural 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 centred 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 – INVESTIGATOR, RESEARCH PLAN, AND BUDGET

Section 1. Items for Evaluation of Investigator

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 SECTION III. STATEMENT OF INSTITUTIONAL SUPPORT). Any comments related to independence would be included here.

Section 2. Items for Evaluation of 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.

Research Plan:

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. 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

Section 3. Items for Evaluation of Budget

1. **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 reductions-use specific amounts and/or percentages.

2. **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 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.

3. **OTHER SUPPORT:** Examine any issues of overlap.

PART II. USE OF HUMAN OR ANIMAL SUBJECTS

1. **PROTECTION OF 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 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 application involves human subjects, evaluate the adequacy of the proposed plans for inclusion of minorities and members of both genders, as well as the inclusion of children. If any of these groups are excluded, is their satisfactory justification for exclusion.
3. **VERTEBRATE ANIMALS.** The peer review committee will evaluate the inclusion of vertebrate animals in the proposed plan. Please consider the strengths and weakness of the overall experimental approach involving vertebrate animals and specifically consider 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 should 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. This assessment should include potential biological and chemical hazards.

PART III – RECOMMENDATIONS

OVERALL RECOMMENDATIONS: Briefly summarize your critique and state your level of enthusiasm using one of these descriptive terms [outstanding, excellent, good, fair, not competitive]. See Scoring Guidelines above for relationship between numeric scores and the descriptive terms used in this section. For outstanding proposals a concise listing of why it is so good is as important as the listing of minor deficits, since the Council looks not only at the numerical score, but also at the level of overt enthusiasm when setting pay-lines. Also include recommendations for improvement and resubmission, including a list of key areas for improvement with specific tips to aid in resubmitting an application.