

MENTORED RESEARCH SCHOLAR GRANT IN APPLIED AND CLINICAL RESEARCH

POLICIES

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This revision supersedes all previous versions.

AMERICAN CANCER SOCIETY, INC.

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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.

MENTORED RESEARCH SCHOLAR GRANT: POLICIES

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1. OVERVIEW OF THE EXTRAMURAL GRANTS PROGRAM OF THE AMERICAN CANCER SOCIETY

The American Cancer Society's Extramural Grants Program seeks to support and promote high impact and innovative cancer-related research across a wide range of disciplines to meet critically important needs in the control of cancer.

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

The Society offers this extramural support in various areas.

RESEARCH GRANTS FOR INDEPENDENT INVESTIGATORS

- **Research Scholar Grants in Basic, Preclinical, Clinical, and Epidemiology Research**—Support for investigator-initiated research projects in basic, preclinical, clinical and epidemiology research. Awards are for up to four years and for up to \$200,000 per year (direct costs), plus 20% allowable indirect costs. *Eligibility Criteria: Investigators in the first six years of an independent research career or faculty appointment are eligible to apply.*
- **Research Scholar Grants in Cancer Control and Prevention: Psychosocial and Behavioral Research**—Support for investigator-initiated research projects in psychosocial and behavioral research, including epidemiologic approaches to psychosocial and behavioral research. Awards are for up to four years and for up to \$200,000 per year (direct costs), plus 20% allowable indirect costs. *Eligibility Criteria: Investigators in the first six years of an independent research career or faculty appointment are eligible to apply.*
- **Research Scholar Grants in Cancer Control and Prevention: Health Services and Health Policy Research**—Support for investigator-initiated research projects in health services and health policy research. Awards are for up to four years and for up to \$200,000 per year (direct costs), plus 20% allowable indirect costs. *Eligibility Criteria: Investigators in the first six years of an independent research career or faculty appointment are eligible to apply.*
- **Research Opportunity Grants**—Provide rapid, one-time funding for novel ideas or for targeting urgent problems with immediate human benefit. Awards are for one year and for up to \$60,000 (direct costs), plus 20% allowable indirect costs. There is no fixed application deadline; however, a letter of intent is required. *Eligibility Criteria: Independent investigators at any stage of their research careers are eligible to apply.*
- **Institutional Research Grants**—Awarded to institutions as block grants to provide seed money for independent junior investigators to initiate research projects. Grants are made for one to three years, and average \$120,000 per year. These grants are renewable.

MENTORED TRAINING AND CAREER DEVELOPMENT GRANTS

- **Postdoctoral Fellowships**—Support for the training of researchers who have received a doctorate providing initial funding leading to an independent career in cancer research (including basic, preclinical, clinical, cancer control, psychosocial, behavioral, epidemiology, health services and health policy research). Awards are for up to three years with progressive stipends of \$37,000, \$39,000, and \$42,000 per year, plus a \$2,000 per year institutional allowance. Depending on

availability of special endowment funds, the Society annually selects one or more of the top-ranked fellowship to be supplemented with such funds.

- **Mentored Research Scholar Grants in Applied and Clinical Research**— Support for mentored research by full-time faculty, typically within the first four years of their appointment, with the goal of becoming independent investigators in clinical, cancer control and prevention, epidemiologic, psychosocial, behavioral, health services and health policy research. Awards are for up to five years and for up to \$135,000 per year (direct costs), plus 8% allowable indirect costs. Up to 10,000 per year for the mentor is included in the \$135,000.
- **Cancer Control Career Development Awards for Primary Care Physicians**—Support for primary care physicians, with a rank of instructor to assistant professor pursuing an academic career with an emphasis on cancer control research, teaching, and practice. Awards are made for three years with progressive stipends of \$50,000, \$55,000, and \$60,000 per year. In addition, salary and benefits for the mentor may be charged to the grant in an amount up to \$10,000 per year.
- **Physician Training Awards in Preventive Medicine**—Awards to institutions to support physician training in accredited preventive medicine residency programs that provide cancer prevention and control research and practice opportunities. Awards are for four years in the total amount of \$300,000, based on an average of \$50,000 per resident training year. These grants are renewable.

PREDOCTORAL TRAINING

- **Doctoral Training Grants in Oncology Social Work**—Awards to doctoral candidates to conduct research related to the psychosocial needs of persons with cancer and their families. Awards are for up to three years with annual funding of \$20,000 (trainee stipend of \$15,000, and \$5,000 for faculty/administrative support).
- **Master's Training Grants in Clinical Oncology Social Work**—Awards to institutions to support the training of second-year master's degree students to provide psychosocial services to persons with cancer and their families. Awards are for one year in the amount of \$12,000 (trainee stipend of \$10,000, and \$2,000 for faculty/administrative support).
- **Doctoral Degree Scholarships in Cancer Nursing**—Awards to doctoral candidates in the fields of cancer nursing research, education, administration, or clinical practice. Awards are for up to four years, with a stipend of \$15,000 per year.
- **Master's Degree Scholarships in Cancer Nursing**— Support for graduate students pursuing master's degrees in cancer nursing. Awards are for up to two years, with stipend of \$10,000 per year.

PROFESSORSHIPS

- **Research Professorships**—Awards to outstanding mid-career investigators who have made seminal contributions that have changed the direction of cancer research. Furthermore, it is expected that these investigators will continue to provide leadership in their research area. In general, applicants will recently have attained the rank of full professor. Up to two 5-year awards are made annually. They can be renewed once. The award of \$80,000 per year can be budgeted at the recipient's discretion.
- **Clinical Research Professorships**—Awards to outstanding mid-career investigators who have made seminal contributions that have changed the direction of clinical, psychosocial, behavioral, health policy or epidemiologic research. Furthermore, it is expected that these investigators will continue to provide

leadership in their research area. The award also may be used to support similarly qualified individuals who are dedicated to bringing advances in basic sciences into the clinical arena and to articulating clinical problems for basic research scientists. Up to two 5-year awards are made annually. They can be renewed once. The award of \$80,000 per year can be budgeted at the recipient's discretion.

- **Professors of Clinical Oncology**—Support for outstanding clinicians and educators to enhance cancer education in medical, dental and other appropriate schools, and foster multidisciplinary cooperation among professionals caring for persons with cancer. Awards are made for three to five years, with a maximum of \$40,000 per year, and may be renewed up to a maximum of 10 years. Applicants must be sponsored and funded by their local American Cancer Society Divisions.
- **Professors of Oncology Nursing**—Awards to outstanding clinicians, educators, and researchers in oncology nursing who will enhance the cancer curriculum in graduate and undergraduate programs. The awards are made for three to five years with a maximum stipend of \$35,000 per year, and may be renewed up to a maximum of 10 years. Applicants must be sponsored and funded by their local American Cancer Society Division.

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 \$45,000 annually.
- **American Cancer Society UICC International Fellowships for Beginning Investigators**— One-year fellowships of up to \$40,000 funded by the American Cancer Society to foster a bi-directional flow of knowledge, experience, expertise, and innovation between countries. Funding preference will be given to applicants who propose to conduct preclinical, clinical, epidemiology, psychosocial, behavioral, health services, health policy research, or cancer control research. However, applications also will be accepted from investigators proposing basic science projects. Application forms may be obtained from the UICC Fellowship Department at <http://fellows.uicc.org/>.

SPECIAL INITIATIVES—REQUEST FOR APPLICATIONS (RFA)

- **Targeted Grants for Research Directed at Poor and Underserved Populations**—Support for research projects that focus on poor or underserved populations and address a variety of clinical, cancer control, behavioral, epidemiologic, health policy, health services, and basic science issues. Applications will be accepted via three mechanisms: Research Scholar Grants, Mentored Research Scholar Grants in Applied and Clinical Research, or Postdoctoral Fellowships. *Eligibility Criteria: Independent investigators at any stage of their research careers may apply for the Targeted Research Scholar Grant; eligibility criteria for Targeted Mentored Research Scholar Grants in Applied and Clinical Research and Targeted Postdoctoral Fellowships are restricted as indicated in the description for these funding opportunities.*

2. DEFINITIONS OF RESEARCH AREAS

Incorporating the recommendations of the Advisory Committee on Research and Medical Grants, the American Cancer Society uses the following definitions:

Basic research: Directed to understanding the events related to the development or prevention of cancer at the molecular, cellular, and organismic levels, as well as the discovery and development of new anticancer drugs or other anticancer therapies.

Preclinical (clinically relevant) research: Aims primarily at providing results applicable to the prevention, diagnosis, or treatment of human cancer or to the rehabilitation of the cancer patient but which are not yet ready for use in humans.

Epidemiology research: Investigates the circumstances under which cancer occurs in populations, including the epidemiology of human behavior and lifestyle factors, as well as molecular epidemiology and gene-environment interactions.

Clinical research: Utilizes human subjects or materials and has direct application to the prevention, diagnosis, or treatment of cancer in the individual or group of individuals under study, or the rehabilitation (including quality-of-life issues) of the patient.

Cancer control research: Investigates how scientifically obtained information can be efficiently and effectively applied to defined groups of people or at the community level to reduce the burden of cancer.

Psychosocial and behavioral cancer research: Directed at understanding and improving the motivational factors in cancer prevention and screening, and the social and emotional impact of cancer and its treatment on individuals, their families, and their caregivers.

Health services research: Examines the interface of the health care system with patients, with the goal of improving access and reducing barriers to optimal health care.

Health policy research: Examines the effects of public policy and laws on public health and access to care, and on reducing barriers to and disparities in health care.

3. 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.

4. 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 initial review. Each committee generally has between 12 and 25 members who are leaders in their areas of expertise, plus up to three "stakeholders." A stakeholder is an individual usually without formal training as a scientist or health professional who has a strong personal interest in advancing the effort to control and prevent cancer through research and training. This interest could stem from an intimate experience with the disease, such as survivorship, a family cancer experience, or being a caregiver.

Depending on the grant applied for, the committees evaluate applications based on some or all of the following criteria: (a) the scientific merit, originality, and feasibility of the application; (b) the qualifications, experience and productivity of the applicant, and all the members of the investigative team; (c) the facilities and resources available; and (d) the promise of the research as related to the control of cancer or to the benefit to be gained by the person with cancer. At the Peer Review Committee meeting, the applications are discussed and a priority score is voted for each one. The evaluations of the committees are provided to the Council for Extramural Grants (the Council), a multidisciplinary panel of senior scientists, most of whom have previously served on a Peer Review Committee, plus up to three stakeholders. After considering the relative merit of the applications, the amount of available funds and the Society's objectives, the Council determines which grants will be funded. No member of a Peer

Review Committee or of the Council may serve concurrently on the Board of Directors or the National Assembly of the American Cancer Society.

Applications that are not funded may be revised and resubmitted. However, only two resubmissions are allowed for Research Scholar Grant and Mentored Research Scholar Grant applications. Resubmitted applications will be reviewed in the same detail and compete on an equal basis with all other new applications and competing renewals. (See Instructions for additional information on resubmission of applications.)

5. SOURCE OF FUNDS

The American Cancer Society obtains its funds principally from public donations collected annually by two million volunteers.

In order to disseminate information about the Society's Extramural Grants Program to our volunteers and to the public, grantees will occasionally be expected to give brief presentations to professional and lay audiences.

6. WHO MAY APPLY

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

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. 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. 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.

An application for a grant must bear the signature of the official authorized to sign for the institution. Signatures of a department head and/or dean of a college are not sufficient.

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

7. TOBACCO-INDUSTRY FUNDING AND CONFLICTS OF INTEREST

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

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

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

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

8. APPLICATION DEADLINES

Applications for grants and awards must be submitted as paper copies in addition to submitting them electronically via proposalCENTRAL. ProposalCENTRAL is a consortium of non-profit granting agencies, developed and hosted by RAMS. Access is available using links provided in the American Cancer Society web site www.cancer.org (see *Instructions*).

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

DEADLINE, REVIEW, NOTIFICATION, AND ACTIVATION SCHEDULE

GRANTS *	Deadline for Receipt of Applications	Peer Review Meeting	Preliminary Notification	Council Meeting	Final 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
Institutional Research Grant	April 1	June	August	Sept.	October	January 1
Physician Training Award in Preventive Medicine	April 1	June	August	Sept.	October	January 1
Research Professorship	April 1	June	August	Sept.	October	January 1
Doctoral Training Grant in Oncology Social Work	April 1 October 15	June January	August March	Sept. March	October April	January 1 Sept. 1
Clinical Research Professorship	October 15	January	March	March	April	July 1
Master's Training Grant in Clinical Oncology Social Work	October 15	January	March	March	April	Sept. 1
Cancer Control Career Development Award	October 15	January	March	March	April	July 1
Doctoral Degree Scholarship in Cancer Nursing	December 1	January	March	March	April	August 1
Master's Degree Scholarship in Cancer Nursing	December 1	January	March	March	April	August 1

* Letters of Intent for **Research Opportunity Grants** may be submitted at any time. Forms for grant applications will be forwarded to investigators who receive an affirmative response to their Letter of Intent.

9. INSTITUTIONAL EXPENDITURES

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

The Society's research grants do not provide funds for such items as:

- Secretarial/administrative salaries
- Tuition (this 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
- Membership dues
- Office and laboratory furniture
- Office equipment and supplies
- Rental of office or laboratory space
- Recruiting and relocation expenses
- Non-medical services to patients
- Per-diem charges for hospital beds
- Construction, renovation, or maintenance of buildings/laboratories

For grants that allow indirect costs, all budget items except equipment are included. See the Instructions for allowable expenditures for Health Professional Training Grants.

10. GRANT PAYMENTS

The American Cancer Society requires that all grant payments, including scholarships, be made to the sponsoring institution, and all checks mailed to that institution.

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. Payments are made to the institution and mailed to the address indicated at the bottom of the contact information page of the application or the grant acceptance form. Acknowledgment of payment is not required.

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

11. ANNUAL AND FINAL PROGRESS REPORTS

The following policies apply to Research Scholar Grants, Mentored Research Scholar Grants, Research Professorships and Clinical Research Professorships, Postdoctoral Fellowships, and Research Opportunity Grants. For all other grants and awards, see "Required Progress Reports" section.

- A. Both nontechnical and scientific progress reports are to be submitted each year within six weeks of the first and subsequent anniversaries of the start date of the grant, and final reports are due within six weeks after the grant has terminated. Reporting forms and samples of nontechnical and scientific progress reports are available at www.cancer.org/research. Select "Funding Opportunities" followed by "Grant Reporting Forms."
- 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.

- C. No reminders will be sent regarding annual reports unless the grantee is being funded through a special donation to the Society. Reminders for final reports will be sent by email. Send reports via email to the Director of Research Promotion and Communication, Donella Wilson, PhD. Reprints may be mailed to her at the address below, or as PDF documents to Donella.Wilson@cancer.org.

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- D. The scientific report should contain:

- One or two pages stating (1) the objective/hypothesis of the project; (2) the progress made toward the specific aims of the original application or an explanation for deviating from the stated aims; and (3) the relevance of the results to the prevention, detection, diagnosis, or treatment of cancer. In addition, it should include:
 - A bibliography of papers acknowledging the Society's support, with publications supported by other sources listed on a separate page.
 - Reprints of publications, along with preprints of any articles in press. Do not include manuscripts submitted for publication. Reprints sent with a previous annual report do not need to be emailed at the time of the final report; however, they should be listed in the bibliography.
 - A list of patents granted or applied for.
 - A brief description of any interactions with the local American Cancer Society, such as speaking at Society events or participating in a Relay for Life team.

- E. The nontechnical report should be a summary of progress in language that a donor or volunteer with no scientific background could understand. It should be ½ to one page long and include: (1) a statement of the relevance of the project to the prevention, detection, diagnosis or treatment of cancer; (2) a brief statement of the method(s) you used or are using; (3) one or two main results that your research achieved; and (4) what the outcome of the project was or will be, if it is successful.

- F. Information submitted as part of a nontechnical or scientific progress report may be made available to the general public; therefore, do not include proprietary/confidential information.

- G. 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, or grants that may be awarded in the future, until reports are received.

12. 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. Annual financial reports are not required. Forms will be provided by the Society or may be downloaded from the web site: www.cancer.org/research. Select "Funding Opportunities" followed by "Grant Reporting Forms."

Signatures of the principal investigator and the institution's financial officer are required. **Any unexpended funds must be returned to the Society, as carryover to a succeeding grant period is not permitted.** Any change in terms such as a no-cost extension will alter the date that the report is due.

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, or grants that may be awarded in the future, 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, for commitments against a grant not paid within 60 days following the expiration date, or any expenditures that exceed the total amount of the award. (See also section 16, "Cancellation.")

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." 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.

14. 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.

15. EXTENSION OF TERM OF GRANT

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. Requests for leave will be handled on a case-by-case basis.

16. CANCELLATION OF GRANT

Intent to cancel a grant must be communicated to the Program Director. In the event a grant is canceled, the institution is allowed only the prorated amount of the award. The Society cannot assume responsibility for expenditures in excess of payments already made to the grantee institution prior to the effective date of cancellation, and all unexpended funds must be returned to the Society. If a grant is to be canceled, please fill out and return the appropriate form.. Forms will be provided by the Society or may be downloaded from the web site www.cancer.org/research. Select "Funding Opportunities" followed by "Grant Reporting Forms."

For Master's Training Grants in Clinical Oncology Social Work, Doctoral Training Grants in Oncology Social Work, Master's Degree Scholarships in Cancer Nursing, and Doctoral Degree Scholarships in Cancer Nursing, withdrawal from the graduate program requires cancellation of the grant and notice in writing. Unexpended funds must be returned to the Society.

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"). 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.
 - 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.

18. OVERVIEW

The Mentored Research Scholar Grant in Applied and Clinical Research is intended to provide resources for junior faculty members to acquire the research training, mentoring and experience necessary for transition into a successful career as an independent investigator. In addition to the research project itself; the activities during the award period must be designed to develop the necessary knowledge and skills in relevant areas through mentoring, and by enrolling in appropriate core curriculum courses and lectures.

19. TYPES OF MENTORED RESEARCH SCHOLAR GRANTS

Mentored Research Scholar Grants in Clinical and Epidemiology Research: Provide resources for junior faculty members to acquire research training, mentoring and experience necessary for transitions into a successful career as an independent investigator in the areas of clinical and epidemiology research.

Mentored Research Scholar Grants in Cancer Control: Psychosocial, Behavioral, Health Policy and Health Services Research: Provide resources for junior faculty members to acquire research training, mentoring and experience necessary for transitions into a successful career as an independent investigator in the areas of psychosocial and behavioral aspects of cancer control, including epidemiologic approaches to psychosocial and behavioral research, or health services and health policy research.

Special Initiative: Targeted Mentored Research Scholar Grants for Research Directed at Poor and Underserved Populations: The American Cancer Society's Extramural Research Grant Program has set-aside funds (up to 10% of the budget) to fund research that addresses the disparity in cancer mortality among the poor and underserved. This special initiative, with the goal of decreasing disparities, provides support for Mentored Research Scholar Grants in Clinical or Epidemiology Research, and in Cancer Control and Prevention Research that *focuses on poor and underserved populations*.

20. ELIGIBILITY FOR MENTORED RESEARCH SCHOLAR GRANTS

1. The following are eligible to apply without prior approval from the American Cancer Society: Candidates who have a doctoral degree and a full-time faculty appointment or equivalent; are within the first four years of their faculty appointment, and are not independent investigators. Faculty who already have established careers with independent research funding (an RO1 or equivalent) and/or extensive research publication record may not apply.
2. Applications will also be considered from:
 - a. Full-time faculty with doctoral degrees who are beyond their first four years of academic appointment *but* who have less than four years research experience.
 - b. Full-time faculty with doctoral degrees who have received career development grants that provide primarily salary support (e.g., American Cancer Society's CCCDA, ASCO Career Development Award). However, support for the combined training may not exceed six years.

Potential applicants 2 (a) and (b) *must* submit a letter of intent and a CV to the appropriate Program Director (listed below) before applying. Only upon receipt of a letter confirming eligibility will they be allowed to submit an application.

- Clinical and epidemiology research: Ralph Vogler, MD, 404-329-7542 or Ralph.Vogler@cancer.org;
- Cancer control: Ronit Elk, PhD, 404-417-5957 or Ronit.Elk@cancer.org.

21. TERMS OF AWARD OF MENTORED RESEARCH SCHOLAR GRANT

A. Amounts and Term of Award

Awards are made for up to five years and up to \$135,000 per year (direct costs) plus allowable 8% indirect costs.

- o Applicants must commit a minimum of 60% of their time to conducting research and developing their research career.
- o The budget for the period of the grant may include the applicant's salary, prorated according to the percent of effort devoted to the project, and additional funds for the research project proposed.
- o Salary and benefits for the mentor may be charged to the grant for up to \$10,000 per year.
- o Salaries of applicant and mentor may not exceed the NCI cap.

Budgets submitted must be realistic estimates of the funds required for the proposed research. Because of limited resources, the Society and its Peer Review Committees expect applicants to exercise considerable budgetary restraint.

B. Resubmission of Unfunded Applications:

Applications that are not funded may be revised and resubmitted.

- o However, only two resubmissions are permitted.
- o The same eligibility criteria apply as in a first submission.
- o Resubmitted applications will be reviewed in the same detail and compete on an equal basis with all other new applications (see INSTRUCTIONS, Section A3.)

C. Renewals and Extensions of Awarded Grants:

- o These grant are not renewable.
- o 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.

22. EVALUATION OF MENTORED RESEARCH SCHOLAR GRANT APPLICATIONS

All of the following will be considered in the review of the application:

1. **Applicant:** Including his/her academic and scientific qualifications, potential to succeed as an independent investigator, and commitment to research as a career. Letters of reference will be evaluated to determine the writer's evaluation of the applicant's research ability and potential, motivation, ability to plan and conduct research, his/her knowledge of the field of study, and ability to work as a member of the research team.
2. **Mentor:** Including the appropriateness of the mentor's research qualifications in the proposed project area, the mentor's role in the project, research productivity and history of experience in fostering the development of cancer researchers.
3. **Research Plan:** A junior investigator's research is not expected to reflect the breadth and depth of a senior scientist. Nevertheless, the research plan must be fundamentally sound including: (a) The scientific and technical merit of the research question; (b) The design, methodology, and feasibility of the study; (c) The relevance of the proposed research plan to the applicant's career objectives; (d) The medical and health significance of the proposed research to cancer prevention, control and/or

treatment; and (e) The appropriateness of the research plan as a vehicle for developing necessary research skills.

4. **Training Plan:** including the appropriateness of the proposed core curriculum studies, courses and lectures in enhancing the research training of the applicant, and their relevance to the applicant's career objectives.
5. **Facilities/Environment:** Including evidence of the institutional commitment to the research development of the applicant; the quality and relevance of the training environment and mentored relationship for the professional development of the applicant; the adequacy of the research facilities and training opportunities for the proposed project; and the appropriateness of the facilities and environmental resources available to the candidate.

23. CHANGE OF INSTITUTION/MENTOR(S)

Recipients of a Mentored Research Scholar Grant may transfer their grant from one institution to another or change their mentor(s) only after receiving written approval from the Society. However, the transfer may necessitate the submission of a revised application, and therefore Mentored Research Scholar Grantees should call their Program Director prior to initiating the transfer.

Change of Institution: Prior to the formal transfer, the American Cancer Society must receive the following:

- The request for transfer in writing, indicating the anticipated transfer date;
- A statement from an administrative official at the original institution relinquishing the grant;
- The final Report of Expenditures from the original institution together with a check for any unexpended funds; forms will be provided by the Society's business office or may be downloaded from the web site at www.cancer.org/research. Select "Funding Opportunities" followed by "Grant Reporting Forms."
- Mentored Research Scholar Grant transfer forms (the title page, contact information page, and assurances and certification page of application form) completed by the appropriate individuals at the new institution indicating acceptance of the grant and documenting the existence of the appropriate resources and mentorship. Forms will be provided by the Society's business office (404-329-7658 or 404-329-7534) or may be downloaded from the web site (see "Grant Reporting Forms").

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

AMERICAN CANCER SOCIETY
MENTORED RESEARCH SCHOLAR GRANTS
INSTRUCTIONS

Effective July 2004
This revision supersedes all previous versions.

AMERICAN CANCER SOCIETY, INC.

Extramural Grants Department
1599 Clifton Road, N.E.
Atlanta, Georgia 30329-4251
Voice: (404) 329-7558
Fax: (404) 321-4669
Web site: <http://www.cancer.org>
Email: grants@cancer.org

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.

MENTORED RESEARCH SCHOLAR GRANTS INSTRUCTIONS

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A. GENERAL INFORMATION

1. APPLICATION SUBMISSION

Applications must be submitted in two formats: paper copies (original application with official signatures plus three copies) and an electronic copy. The electronic version is submitted using links provided in the American Cancer Society web site www.cancer.org/research. **The paper copies of the application must carry the signatures of both the applicant and a representative of the applicant's institution; they constitute the official application and are the version sent out to reviewers.** The applications (both the paper copies and the electronic version) must be received on or before the deadline. The paper copies of the application must be received by the Society's close of business (5:00 PM Eastern time) on the specified deadline date. The electronic applications must be submitted by 8:00 PM Eastern time. If the deadline date falls on a weekend or holiday, applications will be accepted the following business day.

Contact RAMS at 1-800-875-2562 or email, support@ramscompany.com to address any problems using the electronic version of the application

2. FORMATTING THE APPLICATION

Applicants must adhere to the following instructions in completing the Proposal Narrative section. Failure to observe type size specifications and/or page limits will result in the return of the application without reviews:

- **Type size** : Use standard 12-point type for the text, and no smaller than 10-point type 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 5/8 inch all around, unless a form with smaller margins is supplied in the Proposal Narrative.
- **Page numbering**: The first few pages of the application form are considered cover pages and are not numbered. These pages must be submitted in the order that they print followed by the Structured Technical Abstract, which must be printed separately. All subsequent pages, the Proposal Narrative, must be numbered consecutively in the upper right hand corner (do not use page designations such as "9A" or "9B").
- **Appendix**: Material in the application appendix will not be furnished to the entire Peer Review Committee; therefore, it is advisable to include tables, figures, or photographs that are essential for the evaluation of your research plan in the main body of the application. Because photographs do not reproduce well, use original photographs in all copies.

3. RESUBMISSION OF AN APPLICATION

Applications that are not funded may be resubmitted. However, for Research Scholar Grants and Mentored Research Scholar Grants, only two resubmissions are allowed. Please follow these guidelines when resubmitting an application:

- Submit a complete application with a current date—electronic and paper copies.
- The title of the project should be the same as that of the previous application.
- The most recent American Cancer Society application number must be provided where requested.
- Copies of the reviewers' previous critiques, clearly labeled as such, should be placed in the application's Appendix and listed in the Table of Contents.

- A “Reply to Previous Review” should be placed where indicated in the Table of Contents of the Proposal Narrative section of the application and should not exceed 3 pages. 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 should be highlighted (e.g.: bold type, line in the margin, underlining, etc.).

4. NOTIFICATION OF APPLICATION RECEIPT AND REVIEW

Within three weeks after receipt of the application, the applicant will receive an email acknowledgment stating an assigned application number, the Peer Review Committee that will review the application, and the name and telephone number of the Scientific Program Director of the Peer Review Committee. This email will be sent to the address supplied in the Professional Profile at the time of submission.

Preliminary information regarding the status of an application will be emailed. (Copies of the critiques will be provided after review by the Peer Review Committee.) The letter of notification will 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.

Applicants may call the Extramural Grants Department at anytime during the review cycle. The Program Director will shepherd your application through the entire process. For questions concerning the application’s committee review, our staff can be most helpful to you after you have read the reviewers’ critiques.

5. CHANGES TO THE APPLICATION

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

Change of address: Notify the Society in writing of any changes of address, email or phone number, following the submission of an application. Include your name and the application number.

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

6. INTRODUCTION AND ACCESSING THE ACS GRANT APPLICATION SYSTEM

NOTE: In order to use the electronic grant application system, print copies, and submit the application electronically, you must have Adobe Acrobat Reader 5.0. In addition, the system requires a compatible browser: Netscape 7.1 or Internet Explorer 6.0 (and above) for Windows and 5.1 for Mac (and above) is recommended.

- Access the American Cancer Society Research site at www.cancer.org/research.
- Select “Funding Opportunities” followed by “Index of Grants.”
- Select the grant for which you are applying. You are now able to access the electronic grant application process at proposalCENTRAL.
- Once you reach proposalCENTRAL, follow their instructions to complete cover pages, structured technical abstract, and proposal narrative. Please note: Tutorials are available as follows:
 - How to register your institution with proposalCENTRAL (institution officials only)

- How to register as a proposalCENTRAL user
- How to create an application using proposalCENTRAL

ProposalCENTRAL is a consortium of nonprofit granting agencies, developed and hosted by RAMS. If you have problems accessing or using the electronic application process, click on “Help” or contact RAMS Customer Service at support@ramscompany.com or 1-800-875-2562.

7. 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 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 the section and submitting the final version of your application.

Citizenship Status: Check the appropriate box on the Professional Profile. At the time of the application, applicants must be US citizens, noncitizen nationals, or permanent residents of the US. Permanent residents must submit with the application notarized evidence indicating that they have an Alien Registration Receipt Card (I-551) or have been approved for issuance of such card as evidenced by an official passport stamp of the United States Immigration Service and that the form number of the card is I-551. Noncitizen nationals are persons who, although not citizens of the United States, owe permanent allegiance to the US. They are generally persons born in outlying possessions of the United States (e.g., American Samoa and Swains Island).

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

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

Institution Official: In addition to the name and address of the official authorized to sign for the institution, include an address for mailing checks.

Department Chair: Indicate name, department, and email address of the department chair.

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

Additional Mentor: Fill in this section with the same required information as for your primary mentor.

8. GENERAL AUDIENCE SUMMARY

This form is limited to 3,000 characters, including spaces and spelled-out Greek characters. (Note that many Greek characters like β convert to beta.) Using nontechnical language, describe in the space provided how your project relates to cancer in general or specifically to one or more of the categories identified in Priority Areas in the Appendix. This summary must communicate the purpose and rationale of the proposed research or training to people who are not technically trained in the sciences but who are interested in cancer research for a variety of reasons. Be aware that this includes stakeholders, voting members of every peer review committee, who usually do not have formal science or oncology training but have a strong personal interest in controlling and preventing cancer and whose observations about each proposal are respected by the scientists on the committees. This general audience summary should be written in a way that makes the objectives and rationale for the proposal understandable to these stakeholders.

This summary may also be of interest to donors who have the resources to fund cancer research. They frequently are drawn to funding particular types of cancer research, and this summary is used to identify particular projects for special funding opportunities. If the application is funded, this summary will become public information. Therefore, do not include proprietary/confidential information.

This section must not duplicate the scientific abstract. **See the Sample of General Audience Summary in the Appendix for an example of a properly constructed summary.**

9. CANCER RELEVANCE INFORMATION

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

The general public and, specifically, our donors need to be aware of and informed about the Society's research programs so they may continue supporting these programs. The American Cancer Society emphasizes that it is the investigator's responsibility to explain the relevance, importance, and potential impact of the proposed research or training in terms that can be easily understood by neighbors, the voting public, children in schools, and by individuals donating money for cancer research.

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

10. STRUCTURED TECHNICAL ABSTRACT

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

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

Download the Technical Abstract Template and save it to your hard drive. The abstract will need to be uploaded as an attachment to your application.

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. Provide evidence or rationale that supports it.
- **Specific aims:** State concisely the specific aims of the study.
- **Study design:** Briefly describe the study design, emphasizing those elements you consider most relevant to assignment of the proposal for peer review.
- **Cancer relevance:** Provide a brief statement explaining the potential relevance to cancer of the proposed work.

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

11. ASSURANCES AND CERTIFICATION

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

Human subjects. All proposed research projects involving human subjects must be approved by the appropriate Institutional Review Board (IRB). The review date should be recent; certification is invalid if the review date precedes the submission date by more than one year. In applications involving human subjects, applicants must address how HIPAA impacts the proposed research, and how they propose to address potential issues HIPAA may raise for their study.

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 (PHS policy), before the application will be reviewed by the American Cancer Society. IACUC approvals are valid for a maximum of three years. Enter the date of the most recent IACUC approval in the space provided.

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

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 has not been completed before the submission date of the application, select the "IRB pending" radio button on the certification page. Certification of the institutional committee review, clearly labeled with the assigned American Cancer Society application number, must be received within 60 days of the application deadline. If it is not received, the application will be considered incomplete and will not be reviewed.

12. PI DATA SHEET AND RESEARCH PROMOTION INFORMATION

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 when you print the cover pages and does not need to be submitted with your paper copy. **Submit this section electronically only.**

13. COMPLETING ALL APPLICATION SECTIONS AND PRINTING PAPER COPY

- Validate on proposalCENTRAL all sections of the application. This is an essential step. An application that has not been validated cannot be submitted.
- Print **Cover Pages** via proposalCENTRAL. To do so, choose "1. Print The Cover Pages" on the menu.
- If applicable, print copy of **Structured Technical Abstract** document via Word or Adobe. This section is to be submitted behind the **Cover Pages**.
- Print paper copies of all sections of the **Proposal Narrative** via Word or Adobe. Submit this section behind the **Structured Technical Abstract**.
- Print and retain the paper copies of the Demographic and Research Promotion Information and the Cancer Relevance sections for your files. Do not submit this section.
- Prepare the application for your institution's internal authorization process. Obtain the appropriate institutional signatures on the first page of the **Cover Pages**.

14. ASSEMBLY AND SUBMISSION OF PAPER COPIES

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

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

- **Original application (Cover Pages, Structured Technical Abstract [if applicable], Proposal Narrative) with official signatures plus an appendix.**
- **Three copies of the original application, each copy with an attached appendix.**

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

The American Cancer Society
Extramural Grants Department
1599 Clifton Road, N.E.
Atlanta, GA 30329-4251

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

15. SUBMISSION OF THE ELECTRONIC VERSION

- Make all final edits and get all signatures on the paper copy before submitting.
- 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 RAMS at support@ramscompany.com or 1-800-875-2562.
- Once all edits to the application sections have been made and all sections are complete and final, select “**Submit**” on the Manage Proposals page. Click “Yes” to submit. This should be done right after your institution has prepared the application for mailing. You have until 8:00 PM Eastern time on the deadline date to complete the electronic submission. Note that the appendix materials are not submitted electronically.

PLEASE NOTE: YOU WILL NOT BE ABLE TO MAKE ANY CHANGES TO THE FORMS OR UPLOAD ANY MODIFICATIONS TO THE FILES AFTER SUBMISSION.

B. PROPOSAL NARRATIVE

Download the Proposal Narrative Template. Detailed below are the instructions for completing the individual parts of the **Proposal Narrative** section of the application. Upload the document file when complete.

1. TABLE OF CONTENTS (PAGE 1)

Complete the Table of Contents by indicating the appropriate page numbers for each Section; limit the length of the Table of Contents to one page.

2. DETAILED BUDGET (PAGE 2)

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 60 percent of an individual's annual salary is requested then no more than 60 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.

Permanent Equipment. Defined as all items costing over \$500 with a useful life of 2 or more years. List separately and justify the need for each item of equipment.

Supplies. Group into major categories (glassware, chemicals, survey materials, etc.)

Travel Domestic travel only: special consideration will be given for attendance at scientific meetings held in Canada.

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).

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 on a continuation budget page. Administrative pages 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.

Indirect Costs. To help the institution provide proper laboratory and clinical investigation facilities, the Society will permit an indirect cost allowance of up to 8% 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.

Total Amount Requested. 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 application.

3. JUSTIFICATION OF BUDGET (PAGE 3)

Justify all items of equipment costing over \$500, and the need for personnel, supplies, travel, and other miscellaneous items.

4. BIOGRAPHICAL INFORMATION OF APPLICANT

Using the enclosed form titled Biographical Information of Applicant, complete the biographical information requested. Do not exceed three pages for total biographical information.

Citizenship Status. If not a United States citizen, provide notarized evidence of legal, permanent alien resident status.

Education. Beginning with college or equivalent, list degree/year conferred, institution, and field of study.

Training. Postdoctoral fellowships, residency programs, internships. List title of position, mentor's name, institution, and exact dates of training.

Certifications. List professional certifications and credentials with dates.

Appointments. State title, institution, and duration. For each appointment, indicate if the position was independent or mentored. For non-independent appointments, list mentor. If the nature of independence of an appointment requires explanation, use the appendix to justify eligibility.

Professional Activities. List relevant national professional society memberships/activities. Specify organization, national/local status, dates, and roles, e.g., elected officer, chair, member, etc.

Honors And Awards. List academic/professional honors, awards, consultant positions, or activities. Include organization, dates, and national/local status.

Publications. Give complete references for all peer reviewed publications; begin each citation on a new line. If the number of publications is extensive, you may give a partial listing; indicate total number of publications (excluding abstracts, non-peer reviewed articles or book chapters).

5. BIOGRAPHICAL INFORMATION OF KEY PERSONNEL

Provide information for all key personnel involved in the project. 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 (excluding 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.

6. OTHER SUPPORT

List all current awards and all pending and planned applications. Other Support includes both intramural and extramural sources (institutional, for-profit, and not-for-profit, including other grants from the American Cancer Society).

CURRENT SUPPORT: List all current awards; give the source of funds, grant number, title of project, direct costs, period of time covered by the grant, the amount of support for current year (for active grants) and total grant period, and percent effort. Outline the goals of the project in a brief two or three sentence paragraph. This information must be provided for each professional person listed on the budget page (including collaborators) except for consultants. If necessary, an explanatory letter should be included in the appendix to clarify the differences between the present application to the American Cancer Society and currently funded projects.

The following information is required for the principal investigator only. Include in the Appendix, the title page, abstract, specific aims, and budget pages for all grants in effect.

PENDING SUPPORT: List all pending applications to other funding sources for research support. Identify those applications to be considered on an either/or basis with the ACS application for which only one award would be accepted. Give the source of funds, application number (if known), title of project, period of time covered by the application, the amount of direct cost support for current year and total project period and percent effort. Outline the goals of the project in a brief two or three sentence paragraph. If this application to the American Cancer Society is similar to a pending application at another granting agency, indicate whether the proposals are to be considered on an "either/or" basis. It is not necessary to provide any additional information for "either/or" applications in which only one award will be accepted. Please keep the Society up-to-date on the status of all pending applications.

The following information is requested for the principal investigator only. Include in the Appendix, the title page, abstract, specific aims, and budget pages for all pending grants.

PAST SUPPORT, list all past support of the principal investigator to assure that this grant does not duplicate a previous, similar mentored training grant.

The Peer Review Committees will make the final decision regarding any questions of overlap or eligibility.

7. RESEARCH PLAN

Use the form titled “**Plans for Work Under the Grant**” as the first page of the research proposal. The total length of Sections A-D must not exceed 20 pages. Be advised that cogent descriptions are advantageous over long verbose text that approaches the page limits. This page limit does not include the references, which should come at the end of the application. Research 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, if necessary, such proposals should be scaled down to fit the Society's term and budget constraints. Failure to conform to the guidelines on type size, page length, or project scope may impact unfavorably on the priority score, or result in the application being returned to the investigator without review.

PLANS FOR WORK UNDER THE GRANT:

Experience. Summarize your experience to date in clinical activities, teaching, and research. For research experience, describe all previous research experience; state the nature, results, where, when, and with whom the work was conducted as well as your role. Also, describe your short and long term career goals in clinical cancer research and the relevance of your proposed project to them. Describe how you expect the proposed training will achieve these goals and the type of position you wish to obtain following the completion of the award period.

Work Accomplished by You and/or Others. Concisely summarize related work done by others and include any of your own preliminary data that support the proposed project. Reports of research projects accomplished by you that are relevant to this proposal are an important part of the application and should be sufficiently comprehensive to indicate their significance and feasibility. Reprints or preprints may serve in lieu of a detailed report and should be included in an Appendix. Reports of unpublished research are considered confidential.

Aims and Method of Study. Organize this section into the following subheadings.

- (i) **Specific Aims** . Describe briefly in order of priority.
- (ii) **Rationale and/or Significance** . Briefly put the project into perspective.

- (iii) **Statement of Cancer Relevance**. Succinctly describe the relevance to the cancer problem.
- (iv) **Plan of Attack**. Describe in sufficient detail to permit other scientists to evaluate your proposed methods and procedures. 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.

Facilities. Describe briefly the space and equipment available for you to carry out the proposed research.

8. REFERENCES

The list of references should correspond to the citations under headings A-D above. References should be listed numerically in order of their appearance in the text. Each literature citation should include the names of all authors, year of publication, name of the book or journal, volume number, and inclusive page numbers. Providing titles is helpful, but optional. Do not exceed four pages.

9. LETTERS OF RECOMMENDATION

Using the form titled “**Letters of Recommendation**,” list the name, title and address of three persons, other than the proposed mentor, who can critically appraise your qualifications. Ask these persons to send you in a sealed envelope an original letter of recommendation with three copies. They should include comments on character, motivation, maturity, general knowledge, ability to use research techniques, originality, and specialized experience, and training. These letters must be attached to the original of the application and not mailed separately to the American Cancer Society. Your application will be returned to you if these letters are not enclosed.

10. PART II

The following sections must be prepared and signed by the proposed mentor and the department head. Use the page titled **PART II** for Sections 11-14 and, if necessary, use white paper for continuation pages.

11. FACULTY OR SCIENTIFIC APPOINTMENT (OF CANDIDATE)

State the candidate's full-time faculty appointment or equivalent at the activation date of the proposed grant.

12. PROGRAM GOALS AND PROPOSED TRAINING

Describe the overall goals of the proposed program and indicate how the grant, if awarded, will advance the candidate's career as an independent clinical researcher. A description of the specific plans for research training, including core curriculum studies, courses and lectures, and the mentor's role in this program should be provided. Provide a detailed explanation of the activities planned for the period of the award, including clinical, research, teaching, coursework, administrative duties, etc. Estimate the percentage of time allocated to each area. Describe the extent of your involvement in the development and writing of the candidate's research proposal.

13. INSTITUTIONAL RESOURCES AND ENVIRONMENT

Document the existence of an appropriate academic and research environment for the proposed training program. Include departmental and other institutional personnel, ongoing research and other relevant activities, facilities, resources, access to any populations or individuals to be studied, relevant collaborative relationships, etc. Reference any relevant accreditation from professional societies or organizations. Describe how the presence of these resources will directly benefit the candidate. Provide a description of any start-up funds available to support the candidate.

14. TRAINING EXPERIENCE OF MENTOR (S)

Document your background and experience in training clinical and applied cancer researchers. List the researchers you have trained and their current involvement in clinical or applied cancer research. Fully describe your current professional responsibilities and activities. Explain your role in the program proposed for the Candidate. If an additional mentor will be involved in the candidate's training, describe this person's role as well.

15. ABBREVIATED CURRICULUM VITAE OF MENTOR (S)

Using the form titled **Abbreviated Curriculum Vitae of Mentor(s)**, provide biographical information requested. Starting with your present position, list training and experience relevant to area of project, including teaching and clinical responsibilities. List all recent peer reviewed publications and selected earlier key papers. Indicate if this is a partial listing and give the total number of publications, excluding abstracts, non-peer reviewed articles, and book chapters. This section should not exceed two pages. Provide the same information for any additional mentor; the biographical form may be duplicated as needed.

16. SUPPORT OF MENTOR (S)

Using the form titled **Support of Mentor(s)**, list source of support, identifying number, project title, name of principal investigator, percent effort of professional named, dates of entire project period, and direct costs for the entire period and for the current year. Please identify other support under the appropriate heading. *I. CURRENT SUPPORT* should list all current grants. In the appendix, include copies of title page, abstract, specific aims and budget for grants in effect of the mentor(s). *II. PENDING SUPPORT* should list all pending applications.

17. APPLICATION APPENDIX

Appended materials may include letters of support from consultants, recent reprints or preprints, and tables and figures that would lose detail if reduced to fit into the main body of the application. However, the appendix section should not be used to bypass the page limitation. The appendix must be collated in four separate sets, labeled with the name of the principal investigator, and attached to a copy of the application. It is not necessary to number the pages of the appendix, but please list by categories (i.e., reprints, preprints, photographs, letters, etc.) in Table of Contents. Note that the appendix is not duplicated for the entire committee and applicants are urged to keep this section as brief as possible.

APPENDIX A: PRIORITY AREAS

Biology

1.1 Normal Functioning

Examples of science that would fit:

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

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.

1.3 Cancer Initiation: Oncogenes and Tumor Suppressor Genes

Examples of science that would fit:

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

1.4 Cancer Progression and Metastasis

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.

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

Examples of science that would fit:

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

Etiology

2.1-Exogenous Factors in the origin and cause of cancer

Examples of science that would fit:

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

2.2-Endogenous Factors in the origin and cause of cancer

Examples of science that would fit:

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

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

Examples of science that would fit:

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

2.4-Resources and Infrastructure Related to Etiology

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

Prevention

3.1-Interventions to Prevent Cancer: Personal Behaviors that Affect Cancer Risk

Examples of science that would fit::

- Research on determinants of personal behaviors, such as diet, physical activity, sun exposure, and tobacco use, which affect cancer risk.
- Interventions to change personal behaviors that affect cancer risk.

3.2-Nutritional Science in Cancer Prevention

Examples of science that would fit:

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

3.3-Chemoprevention

Examples of science that would fit:

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

3.4-Vaccines

Examples of science that would fit:

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

3.5-Complementary and Alternative Prevention Approaches

Examples of science that would fit:

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

3.6-Resources and Infrastructure Related to Prevention

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

Early Detection, Diagnosis and Prognosis

4.1-Technology Development and/or Marker Discovery

Examples of science that would fit:

- Discovery of markers (e.g., proteins, genes) and/or imaging methods that are potential candidates for use in cancer detection, diagnosis and/or prognosis.

4.2-Technology and/or Marker Evaluation with respect to Fundamental Parameters of Method

Examples of science that would fit:

- Development, refinement and preliminary evaluation (e.g., animal trials and Phase I human trials).
- Preliminary evaluation with respect to laboratory sensitivity, laboratory specificity, reproducibility, and accuracy.

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, receiver-operator characteristics.

4.4-Resources and Infrastructure Related to Detection, Diagnosis or Prognosis

Examples of science that would fit:

- Informatics and informatics networks; for example patient databanks
- Specimen resources (serum, tissue, images, etc.)
- Clinical trials infrastructure.
- Epidemiological resources pertaining to risk assessment, detection, diagnosis, or prognosis.
- Statistical methodology or biostatistical methods.
- Centers, consortia, and/or networks.
- Education and training of investigators at all levels (including clinicians).

Treatment

5.1- Localized Therapies - Discovery and Development

Examples of science that would fit:

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

5.2- Localized Therapies - Clinical Applications

Examples of science that would fit:

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

5.3-Systemic Therapies - Discovery and Development

Examples of science that would fit:

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

5.4-Systemic Therapies - Clinical Applications

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 (vaccines, antibodies), gene therapy, angiogenesis inhibitors, apoptosis inhibitors and differentiating agents.
- Phase I, II or III clinical trials of promising therapies administered systemically.

5.5-Combinations of Localized and Systemic Therapies

Examples of science that would fit:

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

5.6-Complementary and Alternative Treatment Approaches

Examples of science that would fit:

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

5.7-Resources and Infrastructure Related to Treatment

Examples of science that would fit:

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

Cancer Control, Survivorship and Outcomes Research

6.1-Patient Care and Survivorship Issues

Examples of science that would fit:

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

6.2-Surveillance

Examples of science that would fit:

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

6.3-Behavior

Examples of science that would fit:

- Behavior medicine research and interventions.
- Influence of social factors, such as, community, policy, education, and legislation, on behaviors related to cancer control.
- Attitudes and belief systems and their influence on psychological health and on behaviors related to cancer control. For example, how beliefs can alter attempts to seek screening, detection, and treatment
- Interventions to change attitudes and beliefs that affect behavior related to cancer control and cancer outcomes.
- Influences of attitudes and beliefs on compliance to treatment and prevention protocols.

- Psychological or educational interventions to promote behaviors that lessen treatment-related morbidity and promote psychological adjustment to the diagnosis of cancer and to treatment effects.
- Burdens of cancer on family members/caregivers and psychological/behavior issues.

6.4-Cost Analyses and Health Care Delivery

Examples of science that would fit:

- Analyses of cost effectiveness of methods used in cancer prevention, detection, diagnosis, prognosis, treatment, and survivor care/support.
- Development and testing of health service delivery methods
- Interventions to increase the quality of health care delivery
- Impact of organizational, social, and cultural factors on access and quality of care
- Studies of providers, such as geographical or care-setting variations in outcomes
- Effect of reimbursement and/or insurance on cancer control, outcomes and survivorship support.
- Access to care issues.

6.5-Education and Communication

Examples of science that would fit:

- Development of communication tools and methods.
- Education of patients, health care providers, at-risk populations, and general population about cancer.
- Communication to patients regarding therapeutic options.
- Educational interventions to promote self-care and symptom management.
- Communicating cancer risk to underserved populations, at-risk populations, and the general public.
- Alternative teaching methods to communicate therapeutic options and risk reduction behavior to patients or the general public.
- Communication of lifestyle models that reduce cancer risk, such as communication of nutrition interventions.
- Communicating smoking and tobacco cessation interventions.
- Special approaches and considerations for underserved and at-risk populations.
- Education, information, prevention/screening/assessment systems for the general public, primary care professionals or policy makers.
- Training, predictive cancer models, pain management, and surveillance systems for primary care professionals, telehealth/telemedicine applications.
- Communication regarding cancer genetics, managed oncology care, communicating with survivors.
- Barriers to successful health communication.

6.6-End of Life Care

Examples of science that would fit:

- End of Life Care issues including palliative care, psychological interventions with families at end of life, hospice care, pain management for terminally ill patients, etc.

6.7-Ethics and Confidentiality in Cancer Research

Examples of science that would fit:

- Informed consent modeling and development.
- Quality of Institutional Review Boards (IRB).
- Protecting patient confidentiality and privacy.
- Research ethics.

6.8-Complementary and Alternative Approaches for Supportive Care of Patients and Survivors

Examples of science that would fit:

- Hypnotherapy, relaxation, transcendental meditation, imagery, spiritual healing, massage, biofeedback, etc., as used for the supportive care of patients and survivors.

- Discovery, development and testing of complementary/alternative approaches such as diet, herbs, supplements or other interventions that are not widely used in conventional medicine or are being applied in different ways as compared to conventional medical uses.

6.9-Resources and Infrastructure Related to Cancer Control, Survivorship and Outcomes Research

Examples of science that would fit:

- Informatics and informatics networks.
- Clinical trial groups related to cancer control, survivorship, and outcomes research.
- Epidemiological resources pertaining to cancer control, survivorship, and outcomes research.
- Statistical methodology or biostatistical methods.
- Surveillance infrastructures.
- Centers, consortia, and/or networks.
- Education and training of investigators at all levels (including clinicians).
- Psychosocial, economic, political and health services research frameworks and models.

Scientific Model Systems

7.1-Development and Characterization of Model Systems

Examples of science that would fit:

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

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

7.2-Application of Model Systems

Examples of science that would fit:

Application of model systems, including but not limited to:

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

7.3-Resources and Infrastructure Related to Scientific Model Systems

Examples of science that would fit:

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

APPENDIX B: SAMPLE OF GENERAL AUDIENCE SUMMARY

The duplication of the hereditary material, DNA, is the first step in the process that leads to cell division. DNA duplication, also called DNA replication, starts in a coordinated fashion in certain regions of each chromosome. These regions are termed origins of DNA replication. Cancer cells activate their origins in an uncontrolled manner, resulting in uninhibited cell division. Understanding the nature of origin activation will help us to find ways to specifically control cell division in cancer cells. Towards this aim we have started to analyze origins of DNA replication in yeast, which serves as an experimental model system for human cells. Lessons we learn from organisms like yeast should aid us in understanding what goes wrong in human cancer cells. In yeast, we have demonstrated that DNA replication begins at specific positions with a defined origin—a feature that appears to be retained in organisms from yeast to man. This proposal aims to understand the mechanism that determines how the position for replication initiation is chosen. Eventually, we hope to find a way to inhibit replication initiation and render origins inactive in order to block the division of cancer cells.

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.