

AMERICAN CANCER SOCIETY

ALL GRANT INSTRUCTIONS

EFFECTIVE JANUARY 2020

ELECTRONIC APPLICATION DEADLINE: APRIL 1, 2020

PAPER APPLICATION COPY DEADLINE: APRIL 2, 2020

AMERICAN CANCER SOCIETY, INC. Extramural Grants Department 250 Williams Street, NW, 6th Floor Atlanta, GA 30303

> Voice: (404) 329-7558 Fax: (404) 417-5974

Web site: http://www.cancer.org Email: grants@cancer.org

MISSION

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

AMERICAN CANCER SOCIETY

ALL GRANT INSTRUCTIONS

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A. GENERAL INFORMATION

1. AMERICAN CANCER SOCIETY (ACS) GRANT APPLICATION SYSTEM

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

2. FORMAT

- Insert Principal Investigator (PI) name in the header for each template of the application. Do not change the footers on the templates.
- Application documents may be single- or double-spaced (if single spacing, enter a space between paragraphs).
- **Type size**: 12-point Times New Roman or 11-point Arial are the minimum font sizes for the text; 10-point Times New Roman or 9-point Arial font type may be used for figures, legends, and tables.
- Margins: ≥ 0.5 inches all around, unless a form with different margins is supplied in the Application Templates.
- Page numbering:

Number in upper right corner: Proposal Sections. They will be listed in the Table of Contents.

Do not number: Cover pages (Signature Page, Contact Page, General Audience Summary, Structured Technical Abstract, and Proposed Budget, if applicable) and Appendix.

3. UPDATES OF INFORMATION

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

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

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

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

4. REQUIRED INFORMATION

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

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

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

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

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

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

- A **Co-Investigator** is a vital scientific contributor (at the same or a different institution), often bringing a needed expertise to the research team. This person commits some level of measurable effort to the project and is therefore Key Personnel, whether compensated or not.
- A **Collaborator** plays a lesser role in the thinking and logistics of the project than a Co-Investigator. Depending on the role and effort, a collaborator may be designated as Key Personnel and may be compensated.
- A **Consultant** provides expert advice most often for a fee. If the consultant contributes to the scientific development or execution of a project substantively and measurably, he or she should be designated as Key Personnel.

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

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

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

REQUIRED SUPPORTING DOCUMENTS FOR NAMED PERSONNEL

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

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

° If Key Personnel are not being paid, include 'in kind' for dollar amount; percent effort is required.

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

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

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

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

Space: If applicable, indicate the approximate area of independent research space provided by your institution to support your research program, along with the name of the department head

who can verify this commitment. You must insert a value for square footage on the electronic form, even if that number is zero.

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

Technology Transfer Officer (TTO): Guides researchers as their discoveries and inventions become new products and services. They are responsible for technology transfer and other aspects of the commercialization of research that take place at a university. TTOs engage in a variety of commercial activities that are meant to facilitate the process of bringing research developments to market, often acting as a channel between academia and industry.

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

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

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

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

5. GENERAL AUDIENCE SUMMARY

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

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

The general audience summary should *not* duplicate the structured technical abstract but should be written in an understandable way for the general public. Describe concisely the background,

significance, question(s) being asked, information to be obtained, and potential impact of your proposed research. If symbols or Greek characters must be used, they should be spelled out to avoid formatting problems. *See examples of General Audience Summaries in the Appendix.*

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

6. STRUCTURED TECHNICAL ABSTRACT

Note: Not all applications require a structured technical abstract.

The structured technical abstract is a summary of the proposed research or scholarly project for **general scientific** audiences (see Grant Mechanism Appendix for an example).

Organize the abstract into the following sections:

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

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

The American Cancer Society may share the structured technical abstract under a non-disclosure agreement with a third party. Therefore, do not include proprietary information. Please notify us if you do not wish to have your abstract utilized in this manner.

7. PROJECT CODING

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

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

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

8. ASSURANCES AND CERTIFICATION

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

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

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

Human Subjects: All proposed research projects involving human subjects must be approved by an Institutional Review Board (IRB) at an institution approved by the Office for Human Research Protections (OHRP) of the US Department of Health and Human Services (DHHS). Enter the institution's Assurance of Compliance number(s). Copies of the DHHS policy, assured status, and assurance numbers may be obtained from OHRP. Definitions and further clarification can be found at the <u>NIH Office of Extramural Research website</u>.

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

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

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

9. PI DATA

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

10. RESUBMISSION

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

Resubmission guidelines:

- Submit a complete application with a current date for both electronic and paper copies.
- The title of the project can be altered but <u>must</u> be marked as a first or second resubmission.
- Select the appropriate application number from the list of your prior submissions on proposalCENTRAL.
- The review committee code (e.g. TBE, CCE, CPPB, etc.) from the previous application must be provided where requested on the title page.
- Place a "Reply to Previous Review," not to exceed 3 pages, where indicated in the Table of Contents of the Application Templates section. It should clearly address all points raised in the previous review and direct the reader to the specific sections of the text where revisions have been made. Edits in response to reviewers' comments should be designated (e.g. bold type, highlighting, line in the margin, underlining, etc.). Reviewers' previous critiques should be inserted immediately after the "Reply to Previous Review" as indicated in the Table of Contents.

11. APPLICATION SUBMISSION AND REQUIRED SIGNATURES

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

A. Electronic Application

- All application attachments, including the Appendix, must be uploaded as .pdf documents, *except for the signed copy of the front page*, which is to be submitted only with the paper copy. See proposalCENTRAL FAQ or contact support at 1-800-875-2562 for assistance.
- Validate the application on proposalCENTRAL. An application that has not been validated cannot be electronically submitted.
- If any modifications are made to the proposal during the signature process, make certain the electronic and paper versions are consistent.

- Technical questions regarding the electronic application process should be directed to Altum at https://proposalcentral.com/ or 1-800-875-2562.
- Electronic applications must be submitted on proposalCENTRAL by close of business (5:00 PM ET) on the specified deadline date. If the deadline falls on a weekend or holiday, applications will be accepted the following business day.

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

B. Paper Copy

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

- The paper copy must include the signatures (front page) and contact information (second page) of the:
 - Applicant
 - Institutional Official
 - Department Head
- Original signatures are not required; electronic signatures are acceptable. See program-specific instructions for additional required signatures. Please confirm that all required signatures have been collected before mailing the paper copy.
- Print application via proposalCENTRAL. ("Print" on the menu > select "Print Signature Pages and Attached PDF Files"). *Do not print cover pages for an application before validation*.
- Note that cover pages are <u>not</u> uploaded to proposalCENTRAL but are mailed with your paper version.

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

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

12. SPECIFIC INSTRUCTIONS BY GRANT MECHANISMS

RESEARCH SCHOLAR GRANT

INSTRUCTIONS

PREPARING THE APPLICATION

1. COVER PAGES

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

2. APPLICATION TEMPLATES

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

3. TABLE OF CONTENTS (PAGE 1.1)

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

4. BIOGRAPHICAL SKETCH OF APPLICANT (PAGE 2.1)

Complete the NIH Biosketch template, following the formats and instructions provided by the NIH. The Biographical Sketch may not exceed five pages.

5. REPLY TO PREVIOUS REVIEW (PAGE 3.1)

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

All resubmissions must create a new application on proposalCENTRAL.

For Resubmissions: Address the points raised in the previous critiques and direct the reviewer to the specific sections of the text where edits have been made. Revisions should be easily

identifiable in the revised application (e.g.: bold type, italicized, or underline type). This section should not exceed three pages.

6. PREVIOUS CRITIQUES (RESUBMISSIONS ONLY)

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

7 A. RESEARCH PLAN AND ENVIRONMENT (PAGE 4.1)

Section (A) below (Specific Aims) should not exceed 1 page. Sections (B) through (E) below must not exceed 12 pages. This page limit does not include Sections (F) through (J).

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

- **A. Specific Aims**. List the objectives and goals of your proposed research and briefly describe the scientific aims (1 page).
- **B.** Background and Significance. Concisely summarize and critically evaluate relevant work done by your laboratory and others. Specifically state how the successful completion of the work proposed will advance scientific knowledge or aspects of clinical practice that are important for a better understanding cancer or management of cancer patients.

C. Innovation

- 1. If applicable, explain how the application challenges and seeks to shift current research or clinical-practice paradigms.
- 2. Describe any novel theoretical concepts, approaches, methodologies, instrumentation, or intervention(s) to be developed or used, and the advantage they offer over existing ones.
- 3. Explain any refinements, improvements, or new applications of theoretical concepts, approaches, methodologies, instrumentation, or interventions.
- **D. Preliminary Studies.** Provide results of your prior research that are relevant to this proposal; reprints or preprints may be included in the Appendix. Note that the entire application is considered confidential.

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

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

- **F.** Experimental Details (*optional not to exceed 3 pages*). This section is available if more in-depth descriptions of the experimental design, technologies, or assays are needed to convey the specific approaches and procedures proposed.
- **G.** Environment. Describe the space and equipment available to conduct the proposed research (e.g., space designated specifically for your research program, shared space and/or core facilities). The required signature on the cover page by the Department Chair or equivalent verifies an institutional commitment of described research facilities. A detailed description of space and equipment is especially important for non-tenure-track applicants.
- **H. Statement of Cancer Relevance (limit to 250 words).** This section is important to the stakeholders (non-scientific members) on the peer review committees as well as to several general audiences, including donors. Avoid the use of technical jargon.

Describe how the project contributes short- and long-term to the control of cancer. For basic studies relying on experimental models (rather than human cancer cells, tissues, or clinical data) explain how the successful completion of the proposed work will lead to a better understanding of the disease or improve our ability to prevent, detect, treat or manage cancer or cancer patients. For studies involving human subjects, what do you expect to learn about how access to care impacts the overall cancer burden? How could your study improve both delivery of care and cancer outcomes? What effects do you anticipate on the morbidity, mortality, and/or quality of life of your study population? How might further investigations find potential value for health policy? This section must not exceed 250 words.

I. Statement of Science Outreach and Advocacy (not to exceed 1 page). The ACS considers it important that scientists communicate the results of their research to a wide range of communities. Explain the potential impact of your proposed project on your community, and to the ACS's mission of eliminating cancer as a major health problem. Share any previous experiences in science outreach and advocacy. Describe your future plans for disseminating your work in the cancer arena through advocacy, awareness, education, or service. Please include your plans for sharing your research and findings with your non-academic community members and for engaging with community partners in the dissemination process.

J. References. Each literature citation should include title, authors, book or journal, volume number, page numbers, and year of publication. There is no page limitation; this section is not included in the 12-page limit of Sections (B) through (F).

7 B. RESEARCH PLAN AND ENVIRONMENT – RFA – (RSGI) – (PAGE 4.1) THE ROLE OF HEALTHCARE AND INSURANCE IN IMPROVING ACCESS TO CARE AND PERFORMANCE OF CANCER PREVENTION, EARLY DETECTION, AND TREATMENT SERVICES

All cancer health-equity applications must target two or more social determinants of health. Population-based health equity studies must also target two or more levels of influence (individual, interpersonal, organizational, community, or public policy) and focus on achieving health equity. Applicants are at liberty to use more than one model to describe the theoretical underpinning of their research approach.

Section (A) below (Specific Aims) should not exceed 1 page. Sections (B) through (E) below must not exceed 12 pages. This page limit does not include Sections (F) through (J).

- **A. Specific Aims**. List the objectives and goal(s) of the research proposed and briefly describe the Specific Aims in the context of 1 or more of the 4 As of responsible health care reform (availability, affordability, adequacy, administrative simplicity).
- **B.** Background and Significance. Concisely summarize and critically evaluate related work pertaining to access to cancer prevention, diagnostic, treatment, or palliative care services. State how the successful completion of the proposed work will advance health policy knowledge, scientific knowledge, or aspects of clinical practice that are important for better understanding the impact of health policy and/or access to care on cancer patients or patients seeking cancer preventive services.

C. Innovation.

- 1. Explain how the application challenges and seeks to shift current policy, research, or clinical practice paradigms.
- 2. Describe any novel theoretical concepts, approaches or methodologies, instrumentation or intervention(s) to be developed or used, and any advantage over existing methodologies, instrumentation, or intervention(s).
- 3. Explain any refinements, improvements, or new applications of theoretical concepts, approaches or methodologies, instrumentation or interventions.
- 4. If applicable, explain what is unique in your approach to address an important element of access to care and/or health equity in the context of 1 or more of the 4As of responsible health care reform. Describe how this innovation will be enhanced by community or public policy partnerships.

- **D. Preliminary Studies**. Provide results of your prior research that are relevant to this proposal; reprints or preprints may be included in the Appendix. Note that the entire application is considered confidential, including reports of unpublished research.
- **E. Research Design**. Describe your overall hypothesis, proposed methods, procedures, and data analysis in sufficient detail to permit evaluation by other scientists; include your rationale for approaches and analysis. Explain your project's feasibility and how the experiments proposed will address the Specific Aims.

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

- **F.** Potential for Knowledge Transfer and Experimental Details (3 pages or less). *Potential for Knowledge transfer:* Create a clearly defined plan of how the results of the study will be used to develop future research and how it will practically impact local, regional, or national policy; clinical practice; and/or patient interactions with health systems. Concisely describe how the findings will be disseminated. Describe potential application of study findings to the work of ACS CAN.
- **G. Environment.** Describe briefly the space and equipment available to carry out the proposed research. Investigators must have an institutional commitment of research facilities, and the amount of committed space must be verified by the Department Chair or equivalent (signature required on cover page). This section is required and important for all non-tenure-track applicants.
- **H. Statement of Cancer Relevance (limit to 250 words).** This section is important to Stakeholders (non-scientific members) on the peer review committees and to a number of general audiences, including donors. Technical terminology should be avoided. Describe the short- and long-term contributions to the control of cancer.

For studies not directly involving human subjects, explain how the results to be obtained will lead to a better understanding of how health policy impacts cancer prevention, detection, diagnosis, treatment, or palliative/supportive care.

For studies involving human subjects, what do you expect to learn about how access to care impacts the overall cancer burden? How could your study improve both delivery of care and cancer outcomes? What effects do you anticipate on the morbidity, mortality, and/or quality of life of your study population? How might further investigations find potential value for health policy? This section must not exceed 250 words.

- I. Statement of Science Outreach and Advocacy (not to exceed 1 page). The ACS considers it important that scientists communicate the results of their research to a wide range of communities. Explain the potential impact of your proposed project on your community, and to the American Cancer Society's mission of eliminating cancer as a major health problem. Share any previous experiences in science outreach and advocacy. Describe your future plans for disseminating your work in the cancer arena through advocacy, awareness, education, or service. Please include your plans for sharing your research and findings with your non-academic community members and for engaging with community partners in the dissemination process.
- **J. References.** Each literature citation should include title, authors, book or journal, volume number, page numbers, and year of publication. There is no page limitation; this section is not included in the 12-page limit of Sections B-F).

7 C. RESEARCH PLAN AND ENVIRONMENT – PRIORITY AREA FOCUSED ON CANCER HEALTH EQUITY (PAGE 4.1).

Key Words

ACS Cancer Health Equity definition: Cancer health equity involves everyone having the fair and just opportunity to prevent, detect, treat, and survive cancer. Health inequities and health disparities may be characterized by age, gender, disability status, ethnicity/race, nativity and immigration status, geography, income, language, social class and sexual orientation.

Social Determinants of Health: This refers to macro-environmental conditions where people are born, grow, live, work and age along with the available systems supporting health. Research may include aspects of the following domains of the social determinants of health inequities: economic; education; neighborhood and built environment; policy; social and community context; or factors impacting access to and provision of high-quality care.

Levels of Influence: individual, interpersonal, organizational, community, or public policy.

Section (A) below (Specific Aims) should not exceed 1 page. Sections (B) through (E) below must not exceed 12 pages. This page limit does not include Sections (F) through (J).

- **A. Specific Aims.** List the objectives and goal(s) of the research proposed and briefly describe the Specific Aims in the context of the social determinants of health your research will address to contribute to achieving health equity.
- **B.** Background and Significance. Concisely summarize and critically evaluate related work pertaining to social determinants of health and cancer health equity topics for which will be the focus of your research. State how successful completion of the proposed work will advance cancer health equity related to some aspect of the cancer control continuum-

prevention, screening and early detection, diagnosis, treatment, palliative care or survivorship.

C. Innovation.

1. Explain how the application challenges and seeks to shift current social, political, research, or clinical practice paradigms in relation to health equity.

2. Describe any novel theoretical concepts, approaches or methodologies, technologies or intervention(s) to be developed or used, and any advantage over existing methodologies, or intervention(s)addressing cancer health equity.

3. Explain any refinements, improvements, or new applications of theoretical concepts, models, methodologies, technologies, or interventions.

4. If applicable, explain what is unique in your approach to address an important issue regarding the social determinants of health and cancer health equity. Describe how this innovation been enhanced by community, health systems or public policy partnerships.

- **D. Preliminary Studies.** Provide results of your prior research that are relevant to this proposal; reprints or preprints may be included in the Appendix. Note that the entire application is considered confidential, including reports of unpublished research.
- E. Research Design. Describe your overall hypothesis, proposed methods, procedures, and data analysis in enough detail to permit evaluation by other scientists; include your rationale for approaches and analysis. Explain your project's feasibility and how the experiments proposed will address the Specific Aims. All cancer health-equity applications must address two or more social determinants of health in relation to the following domains: economic; education; neighborhood and built environment; policy; social and community context; or factors impacting access to and provision of high-quality care. Applicants proposing multi-level health equity research must also target two or more levels of influence (individual, interpersonal, organizational, community, or public policy) and focus on contributing to achieving health equity. Applicants are at liberty to use more than one model to describe the theoretical underpinning of their research approach. Discuss potential difficulties and limitations of your proposed methods and provide alternative approaches. Inclusion of an experimental time-line can be helpful.
- **F.** Potential for Knowledge Transfer and Experimental Details (3 pages or less). Potential for Knowledge transfer: Create a clearly defined plan of how the results of the study will be used to develop future research and how it will practically impact cancer health equity. Concisely describe how the findings will be disseminated. Describe potential application of study findings to the work of ACS.

- **G.** Environment. Describe briefly the space and equipment available to carry out the proposed research. Investigators must have an institutional commitment of research facilities, and the amount of committed space must be verified by the Department Chair or equivalent (signature required on cover page). This section is required and important for all non-tenure-track applicants.
- **H. Statement of Cancer Relevance (limit to 250 words).** This section is important to Stakeholders (non-scientific members) on the peer review committees and to several general audiences, including donors. Technical terminology should be avoided. Describe the short- and long-term contributions to the control of cancer in the context of cancer health equity.
- I. Statement of Science Outreach and Advocacy (not to exceed 1 page). The ACS considers it important that scientists communicate the results of their research to a wide range of communities. Explain the potential impact of your proposed project on your community, and to the American Cancer Society's mission of eliminating cancer as a major health problem. Share any previous experiences in science outreach and advocacy. Describe your future for disseminating your work in the cancer arena through advocacy, awareness, education, or service. Please include your plans for sharing your research and findings with your non-academic community members and for engaging with community partners in the dissemination process.
- J. References. Each literature citation should include title, authors, book or journal, volume number, page numbers, and year of publication. There is no page limitation; this section is not included in the 12-page limit of sections B-E.

8. DETAILED BUDGET

Complete the budget page located online at proposalCENTRAL

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

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

The costs to the institution of employee fringe benefits should be indicated as a percent of the employee's salary. The amount of fringe benefits requested must be prorated to the salary requested. (For example, if 50 percent of an individual's annual salary is requested

then no more than 50 percent of that individual's annual cost for fringe benefits can be requested.)

Please Note: For definitions of key personnel refer to General Policies - Required Information.

B. Equipment.

- **Permanent equipment** Defined as items of nonexpendable property with a purchase cost per unit that equals or exceeds \$5,000 with a useful life of more than one year. List separately and justify the need for each item of permanent equipment. Note: the cost of permanent equipment is not included in the Direct Cost total used to calculate Indirect Costs.
- Small or expendable equipment Defined as expendable property with a purchase cost per unit that is less than \$5,000 and/or that has a short service life (<1 year). Note: the cost of small or expendable equipment should be included in the Direct Cost total used to calculate Indirect Costs.
- General purpose equipment Equipment such as computers used primarily or exclusively in the actual conduct of the proposed scientific project are considered direct cost and may be included in the Direct Cost total used to calculate Indirect Costs. Computers or other general-purpose equipment that will be used on multiple projects or for personal use should not be listed as a direct cost and should not be included in the calculation for indirect cost.
- **C. Supplies.** Group supplies into major categories (e.g. glassware, chemicals, radioisotopes, survey materials, animals, etc.).
- **D. Travel**. Domestic travel only: special consideration will be given for attendance at scientific meetings held in Canada.
- **E.** Miscellaneous Expenditures. List specific amounts for each item. Examples of allowed expenditures include publication costs and special fees (e.g., publication costs, pathology, computer time and scientific software, and equipment maintenance).
- F. Subcontracts. If any portion of the proposed research is to be carried out at another institution, enter the total costs (direct) on the online budget detail page on proposalCENTRAL. Then provide a categorical breakdown of costs using the Subcontractor Budget and Justification form, using one form per subcontractor. Upload the form(s) when complete, entering the subcontractor's name in the "describe attachment" field. Note: indirect costs for the subcontract budget may be claimed by either the primary or the secondary institution, but not both.

Subcontracts for the research project may be with public or private institutions, provided they do not violate ACS policies. Subcontracts involving a contractor residing outside the borders of the United States are not permitted, unless the applicant can document that it is not feasible to have the work performed within the United States.

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

- **G. Indirect Costs**. To help the institution provide proper laboratory and clinical facilities, the Society will permit an indirect cost allowance of up to 20% of the direct costs, excluding permanent equipment. Indirect costs for a subcontract budget may be claimed by either the primary or the secondary institution, but not both. Indirect costs can be provided to the secondary institution through negotiation with the Principal Investigator's institution but the total amount of indirect costs, inclusive of subcontracts, may not exceed 20% of the award.
- H. Total Amount Requested. Budget totals should reflect a maximum duration of 4 years. For Research Scholar Grant applicants proposing large multilevel health equity studies: An application submitted as a large multi-level health equity study, may budget a maximum duration of 5 years and may budget up to \$200,000 direct cost per year and 20% indirect cost per year. The total budget may not exceed \$1,200,000 for the project period. Applicants must provide a strong rationale, preliminary data, and suitable approach that demonstrate expertise in conducting large studies and justify the proposed time and budget.

The Society and its peer review committees expect applicants to show judicious use of proposed funds in all grant applications. Enter the sum of all years of requested support, including indirect costs, and round to the nearest thousand dollars. Transfer this figure to the title page of the online application.

9. JUSTIFICATION OF BUDGET

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

10. BIOGRAPHICAL INFORMATION OF KEY PERSONNEL (PAGE 5.1)

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

11. OTHER SUPPORT (PAGE 6.1)

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

The only exceptions are:

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

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

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

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

Please keep the Scientific Director current on the status of pending applications that have scientific overlap, would interfere with the PI's budgeted effort on the ACS proposal, or could compromise RSG eligibility (i.e., more than one R01 or R01-like grant as PI at the time of application).

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

These details should be confirmed by the Department Chair in the Statement of Institutional Support included in Section 14, below.

Non-tenure track applicants should also include a more detailed description of the space committed to the project. If the applicant is in the same department as a previous mentor, provide information on the relationship between the mentor's research space, and the space available for the project, and the relationship between funded research projects in the mentor's laboratory and the present application. Documentation should be included in the Statement of Institutional Support (Section 14, below) written by the Department Chair.

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

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

13. COMPLIANCE STATEMENTS (PAGES 8.1 – 8.3)

Human Subjects

Selection of study population. When conducting research on humans, provide the rationale for selecting your target population. Include the involvement of children, minorities, and especially vulnerable populations such as neonates, pregnant women, prisoners, institutionalized individuals, or others who may be considered vulnerable populations or others who may be considered vulnerable populations of a grant.

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

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

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

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

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

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

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

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

Vertebrate Animals

Provide your rationale for using live vertebrate animals including the:

- 1. Necessity for using the animals and species proposed;
- 2. Appropriateness of the strains, ages, genders of the animals to be used;
- 3. Justifications for, and appropriateness of, the numbers of animals proposed. When completing the Targeted Enrollment Table, select non-human subjects research and check the box that most appropriately describes your research.

Biohazards

Briefly describe whether any materials or procedures proposed are potentially hazardous to research personnel, equipment, and/or the environment. What protections will mitigate such risks? Include biological or chemical hazards.

Authentication of Key Biological and/or Chemical Resources

Briefly describe methods to ensure the identity and validity of key biological and/or chemical resources to be used in the proposed studies. These resources may or may not be generated with ACS funds and:

• may differ from laboratory to laboratory or over time;

- may have qualities and/or qualifications that could influence the research data; and
- must be integral to the proposed research.

These may include, but are not limited to, cell lines, specialty chemicals, antibodies, and other biologics. Researchers should transparently report how they have authenticated key resources, so consensus can emerge.

Standard laboratory reagents that are not expected to vary need not be included in the plan (e.g. buffers and other common biologicals or chemicals). After reviewers assess the information you provide in this Section, their questions will need to be addressed prior to an award.

In this section, focus *only* on authentication and/or validation of key resources to be used in the study. Include all other information within the page limits of the research strategy. Applications that fail to comply may be dismissed.

Priority Focus on Health-Equity Research in the Cancer Control and Prevention Research Grants Program (750-words)

Applicants proposing health-equity research must upload a Cancer Control and Prevention Health Equity Statement (**Page 8.3**). In it, summarize the targeted area(s) of health equity, study population, and how the proposed research can contribute to improving health equity relevant to cancer.

How will your anticipated findings advance the field? This must pertain to an aspect of the cancer continuum and one or more of the social determinants of health. Examples of research in this area include, but are not limited to, improvements in:

- risk reduction behaviors;
- access to cancer prevention;
- early detection, diagnosis, and/or treatment services;
- reducing cancer morbidity, mortality, symptom burden, or costs; and
- quality of care, quality of life, or health policy impact.

14. STATEMENT OF INSTITUTIONAL SUPPORT (PAGE 9.1)

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

The letter should also describe the Department's long-term goals for the applicant's career.

15. APPENDIX TO APPLICATION

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

- Letter from ACS Eligibility Committee confirming eligibility (if applicable)
- Recent reprints or preprints (optional)
- Clinical protocols (if applicable)
- Logic model for program projects and dissemination and implementation pilots (if applicable)

APPENDIX A: REVIEWER GUIDELINE CRITERIA

PART I CANDIDATE

Investigator:

Provide an overall evaluation of the candidate's academic, clinical, and/or scientific qualifications, their potential to succeed as an independent investigator, and their commitment to a career in cancer-related research. Assess the qualifications of the applicant considering the following items: goals and commitment to cancer-related research; past education; past training – board eligible or board certified, if appropriate; past research experience; number and impact of previous publications; and overall appropriateness of the candidate for an RSG.

The RSG award is intended for fully independent scientists with clear evidence of institutional commitment (e.g. tenure-track, start-up funds, independent space, senior author publications) as confirmed in the Letter of Support from their Department Chair (in grant application STATEMENT OF INSTITUTIONAL SUPPORT – See template 9.1).

REPLY TO PREVIOUS REVIEWS [IF APPLICABLE]

Note whether this is a resubmission and comment on adequacy of response to critiques.

PART II RESEARCH PLAN

It is critical to evaluate rather than summarize the research plan. Please be specific and detailed in your critique including, at a minimum, the following elements:

1. Significance: Does the project address an important problem or a critical barrier to progress in the field? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice improve? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

2. Cancer Relevance: How is this research relevant or how will it impact persons at risk for, or living with, cancer or their family/caregivers? The relevance to cancer may be indirect, but the connection must be clearly articulated by the applicant.

3. Innovation/Improvement: What is the potential that the proposed study will challenge and seek to shift current research understanding or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Does the research propose meaningful improvements or address critical gaps?

4. Investigator/ Research Team: Does the PI and research team have the training and experience needed to carry out the proposed research?

5. Approach: Are the study design, methods for implementation, data collection and analysis appropriate for answering the research question. Where appropriate, are proposed recruitment and/or case ascertainment methods well developed? Is the sample size adequate? Is the research timeline realistic? Are potential pitfalls, alternative approaches, and future plans articulated?

6. Environment: Will the scientific environment and institutional support contribute to the probability of success? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements? Are there competitive start-up funds to support the candidate's independent research program?

7. Statement of Science Outreach and Advocacy (FEEDBACK OPTIONAL, THIS SECTION SHOULD NOT BE INCLUDED IN CONSIDERATION OF SCORING): Does the outreach and advocacy plan present any concerns (including, but not limited to, research compliance, participant safety, and/or feasibility)? Do you have any suggestions to improve the plan?

PART III BUDGET

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

It is the policy of the American Cancer Society not to fund projects that are supported all or in part by another agency.

PART IV COMPLIANCE STATEMENTS

1. Human Subjects. If applicable, evaluate the plans for protection of human subjects from research risks justified in terms of the scientific goals and research strategy proposed. For example, are the potential benefits and risks to subjects articulated reasonable and appropriate given the study design? Are their plans for conducting sub-analysis by group, data security and confidentiality, biohazards and data and safety monitoring adequate.

2. Inclusion of Women, Minorities, and Children. When the proposed project involves human subjects, evaluate the adequacy of the proposed plans for inclusion or exclusion of minorities, male and female genders, as well as children.

3. Vertebrate Animals. Evaluate the plan for live, vertebrate animals as part of the scientific assessment according to the following points: 1) necessity for the use of the animals and species proposed; 2) appropriateness of the strains, ages, and gender; 3) justifications for, and appropriateness of, the numbers of animals.

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

Priority Focus on Health Equity Research in the Cancer Control and Prevention Research Grants Program (ONLY for Cancer Control and Prevention applications)

For health equity applications in Cancer Control and Prevention, reviewers will assess the potential impact of the proposed study, if the specific aims are successfully accomplished. For example, how will this research: (1) substantially improve equity in access to cancer prevention, early detection, diagnosis, and/or treatment services; (2) accelerate efforts to reduce cancer burden or costs, improve quality of care, delivery of care or quality of life; or (3) impact public policy to advance health equity relevant to cancer? The reviewer critique should include a summary of the targeted area(s) of health equity proposed, the study population, determinates of health that will be explored and the levels of influence (individual, interpersonal, organizational, community, or public policy) being targeted.

INSTITUTIONAL RESEARCH GRANT

INSTRUCTIONS

PREPARING THE APPLICATION

Please read carefully the requirements set forth in the Policies, Institutional Research Grants before completing the application. Prospective applicants who have questions should contact the Scientific Director for clarification prior to submission of an application. Questions should be directed to:

Virginia (Ginger) Krawiec, MPA Scientific Director, Institutional Research Grants Stella Jones, Program Manager 404-329-5734 stella.jones@cancer.org

1. APPLICATION TEMPLATES

An application includes several sections that must be uploaded before the online application is submitted. Templates for these sections are available once an application is started on proposalCENTRAL; download to a computer and complete offline using word processing software. Detailed below are the instructions for completing the individual sections. *Convert the sections into .pdf documents before uploading. Please see proposalCENTRAL's FAQ or call support at 1-800-875-2562 if you need assistance.*

2. TABLE OF CONTENTS (PAGE 1.1)

The Table of Contents is pre-numbered, corresponding to the page numbers for the first page of each application section. All pages of the application should be numbered sequentially. To complete the Table of Contents for a new application, delete the (Renewals Only) section. To complete the Table of Contents for a renewal application, delete the (New Applications Only) section.

3. REPLY TO PREVIOUS REVIEW (RESUBMISSIONS AND RENEWALS) (PAGE 2.1)

IF THE APPLICATION IS A NEW SUBMISSION, upload the provided template with "Not Applicable" in the body.

IF THE APPLICATION IS A RESUBMISSION, then complete this section to clearly and briefly address the points raised in the previous reviews and direct the reader to the specific sections where text revisions have been made. Do not exceed three pages. Text changed in response to reviewers' comments should be identifiable in the revised application (e.g. bold type, line in the margin, underlining, etc.).

IF THE APPLICATION IS A RENEWAL, the peer review committee reviews the critiques of the most recent application as part of the evaluation of a new proposal. Effective January 2012, **renewal** applications also must include the critiques of the previous application, and document progress made toward addressing the points made by the reviewers by completing the Reply to Previous Review.

Insert copies of the previous critiques immediately after the Reply to Previous Review, as illustrated in the Table of Contents. You may download electronic copies of these critiques from your "Submitted" page on proposalCENTRAL. Select the link to "View Review Info", then "View Summary Statement" and save the document to your computer. Upload the document to your application with the other proposal sections.

4. DESCRIPTION OF THE PROGRAM (PAGE 3.1)

This section must be limited to four pages and should not duplicate information provided elsewhere in the application. It should provide an overview of the academic environment for the proposed IRG program, including:

• The nature of the institution, e.g., university, academic health center, freestanding research facility, etc. The principal investigator should also use this section to describe unique aspects of the institution, such as service to special populations, location, or any special resources.

If a <u>consortium program</u> is proposed, describe the arrangement with the other institution(s), including information about:

- the relationship between the institutions;
- the status of cancer research at the other site(s);
- the expected growth in the IRG applicant pool;
- the inclusion of faculty from the other institution on the IRG review committee [along with biographical sketches (see Section 7)]; and
- \circ the opportunities for their beginning investigators to access mentoring resources.

A memorandum of agreement or similar document may also be included in the application Appendix.

- Ongoing and planned cancer-related activities, especially the cancer research program. Describe any strategic efforts underway at the institution to expand cancer research and other cancer-related activities.
- The importance of this grant to the institution as a whole, especially how the IRG will be used to leverage other resources to support cancer research and beginning investigators. If this application is a renewal of an IRG that is no longer in effect, please explain funding lapses of more than one year.
- Information about the institution's replenishing pool of beginning investigators interested in cancer research. Specifically, show the percentage of new faculty annually recruited to the institution, what proportion of these are beginning **independent** researchers interested in

cancer, and the success rate of their junior faculty in obtaining national competitive funding in the area of cancer research.

• Renewal applications should also highlight any outstanding accomplishments by the individual awardees, both present and past. If titles are different from the standard academic titles, the institution should explain (e.g., is an "instructor" an independent principal investigator?).

5. CAREER DEVELOPMENT ACTIVITIES FOR BEGINNING INVESTIGATORS (PAGE 4.1)

Describe the institution's ongoing or new activities to promote career development that are available to junior faculty affiliated with the IRG program. Examples of these activities include but are not limited to:

- mentoring and advisement by senior faculty with established cancer research careers;
- guidance on publishing scientific results;
- seminars on grant writing and research funding, teaching, mentoring, publishing, personnel/lab/office management, etc.;
- critiques of draft applications for national peer reviewed research grants;
- guidance on developing collaborative research relationships, and
- advice on balancing an academic career and one's personal life.

6. COMPOSITION OF LOCAL INSTITUTIONAL RESEARCH GRANT REVIEW COMMITTEE (PAGE 5.1)

The principal investigator of the grant will chair this committee. Describe the qualifications of the principal investigator to lead the IRG program, including research interests and accomplishments, mentoring experience, grant funding history, publication history, and administrative experience.

If this is a renewal application, and a change in the chair of the local IRG review committee/IRG principal investigator has occurred or is being proposed, please explain the reason for the change.

The local IRG Review Committee should be composed of representatives from all the health science schools and colleges of the institution. Summarize the committee composition, using the example below for format.

	Basic	Clinical	Cancer Control and	Total
	Research	Research	Population Sciences	
Professor	5	2	2	9
Associate Professor	2	2	3	7
Assistant Professor	2	3	1	6
Other			1	1
Total	9	7	7	23
Percentage	40%	30%	30%	100%

Using the table provided, list the names, titles, departments, schools, and research interests of the members of the local IRG Review Committee. *Include the names and titles/affiliations of the ACS representatives*.

7. BIOGRAPHICAL INFORMATION (PAGES 6.1 & 7.1)

Use the Biographical Sketch template provided, or copies thereof, to provide the requested information on all *academic* members of the local IRG Review Committee. Include committee members' research grant funding history, which will be used to assess both grant experience and ability to guide beginning investigators.

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

Publications. Give complete references for all peer reviewed publications over the last five years, including titles; 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, and book chapters).

This information is required regardless of whether you have provided it before, since previous applications are not available to the Society's Peer Review Committee on Institutional Research Grants. Do not exceed three pages per person for total biographical information. Please see the **POLICIES: ANSWERS TO FREQUENTLY ASKED QUESTIONS** for additional information about the local IRG Review Committee.

8. DOCUMENTATION OF INTERACTION WITH THE LOCAL AMERICAN CANCER SOCIETY (PAGE 8.1)

A demonstrated interaction among the local American Cancer Society, the ACS Cancer Action Network, and the institution, *especially the IRG pilot project grantees*, is an essential part of the application. These interactions are particularly useful ways for increasing the awareness of ACS Region volunteers and staff about the research that their effort and dollars support. To foster communication about the IRG Program with volunteers and staff, institutions are **expected** to include one or two Region representatives as members of the local IRG Committee. For new applications, the principal investigator and the institution should work together with the appropriate local American Cancer Society staff to formulate an interaction plan if none exists. Contact the National Scientific Director for Institutional Research Grants for assistance if needed. A letter of support from the Region may be included in the Appendix. Please see the **POLICIES: ANSWERS TO FREQUENTLY ASKED QUESTIONS** for examples of successful interactions.

9. PROCEDURE FOR PUBLICIZING AVAILABILITY OF FUNDS (PAGE 9.1)

Explain how all qualified individuals are to be informed about the availability of these funds, e.g., university newsletters, memoranda, notices. Include examples in the Appendix.

10. HOW ALLOCATIONS ARE TO BE MADE (PAGE 10.1)

Explain in detail the local IRG Review Committee operations. This description should include:

- The processes for member selection, rotation, and participation in the review process, including how conflicts of interest are handled.
- The committee review process, including the frequency and timing of meetings, the application assignment, review and ranking process (including special interest award applications, *and if relevant, the procedure for competitively renewing grants for a second year*). If the IRG review committee relates in some way to another intramural grant reviewing body, explain how the IRG application review and the allocation of IRG funding are kept separate.
- The type of feedback provided to applicants, as well as how awardees are made aware that their support comes from the American Cancer Society. Programs are encouraged to provide written feedback to all applicants and to include unsuccessful applicants in any mentoring activities that are offered to IRG pilot project grant recipients.
- Any other activities related to the IRG program, e.g., presentations of the results of IRG-funded projects, symposia, etc.

11. JUSTIFICATION FOR FUNDS REQUESTED (PAGE 11.1)

This section must include the table provided in the template document; complete it by inserting the information requested about your current level of IRG funding (if applicable) and the funding request for the current application. (These latter amounts must agree with the numbers provided on the cover page of your printed application.)

For estimating the amount of funds to be requested, it may be assumed that approximately 30% of the individual applications received for review by the local IRG Review Committee will be funded. Effective with 2020 IRG applications, <u>four</u> pilot project grants per year is the maximum that may be requested. The standard amount for pilot project grants is \$30,000 per year; if smaller awards are proposed, please explain the rationale. Institutions are discouraged from awarding less than the maximum amount from ACS funds.

If matching funds are to be provided by the institution, please explain their nature and amount. Institutions are encouraged to supplement the pilot project awards—thereby increasing the individual \$30,000 award amount—rather than provide funds to increase the number of pilot project awards.

Applicant Pool: The amount of funds requested must be based on the size of the pool of applicants eligible for pilot project grants. Describe here the number of beginning investigators engaged in cancer research who are not principal investigators on nationally competitive research grants (but who are eligible to apply for them), and the anticipated number of new junior faculty positions available during a given year within the institution or group of institutions.

Special Interest Awards: If the application includes st for one Special Interest pilot SUSPENDED project award each year, specific justification d. Describe how this area (see the Policies for appropriate areas of f on's programmatic goals and its suitability to support the program. In the area, and the pool of potential applicants.

Other Support: All applications must justify the need for funding to permit junior faculty to initiate promising pilot projects in cancer research. State other sources and amounts of pilot project funding available (local, institutional, Cancer Center Core Grant, etc.). **Indirect Costs:** Indirect costs are not allowed on IRG.

If this is a <u>renewal</u> application, delete the following two sections from the Table of Contents and the templates will not be used.

12. DOCUMENTATION OF APPLICANT POOL SIZE (NEW APPLICATIONS ONLY) (PAGE 12.1)

List all junior faculty who are interested in cancer-related research, including any anticipated additional positions . <u>Include</u> approved but unfilled positions marked as TBD; <u>exclude</u> junior faculty who already hold national competitive research grants. (Information about the latter group is requested under **DESCRIPTION OF PROGRAM**.) Refer to the **POLICIES: REQUIREMENTS FOR APPLICANTS FOR IRG PILOT PROJECT GRANTS** for specific eligibility guidelines.

13. EXAMPLES OF RESEARCH TO BE SUPPORTED (NEW APPLICATIONS ONLY) (PAGE 13.1)

Using the forms provided, include up to five examples of research to be supported if funds are awarded, along with information about the investigator and the proposed pilot project. Limit each individual project description to one page.

Applications for competitive renewal of an IRG must include Tables I through VI (following). If this is a new application, delete these sections from the Table of Contents and their templates will not be used:

14. SUMMARY TABLES (PAGES 12.1 – 17.1)

Using the templates for Tables I through VI, please provide the requested information for the past <u>seven</u> award years, or for the number of years in effect for grants of less duration. <u>Tables</u> <u>must be accurate, internally consistent, and responsive to instructions</u>. Where term dates are requested, these should reflect the start and end dates of the **pilot projects**.

Note: Supplemental materials will be accepted after the April 1 deadline through May 15. However, these items should be limited to updated information about past awardees, i.e., additional grants received, articles published, or information about the recent activities of the institution's IRG Review Committee.

TABLE I. SUMMARY OF PILOT PROJECT GRANTS

Starting with the just completed grant year (January – December) and working backward, please provide a summary of pilot project grants to individuals for the last <u>seven</u> years. (For first time renewals, the number of years will be less.) Provide the academic title of the investigator at the time of the award, and also the current title and institution, if different from the awarding institution.

The award amount should reflect any supplemental funds provided by the institution. In these cases, the amount may be more than the \$30,000 limit per individual award. However, do not include pilot projects that were funded in their entirety by the institution. Please describe these in the budget justification.

TABLE II. SUMMARY OF UNFUNDED APPLICATIONS

Starting with the most recently completed grant year (January-December) and working backward, provide the information requested. If an application with a better score than a funded application is unfunded in any cycle, explain the reason in a footnote to the table.

TABLE III.SEVEN YEAR SUMMARY OF SUBSEQUENT PUBLICATIONS FOREACH GRANTEE

For all of the awardees listed in TABLE I (except those currently receiving funding), provide the information requested. List only published or in-press peer reviewed publications *(first or senior author only)*.

In the first two columns, use a check mark to indicate if the article is:

- Based on work supported by the IRG pilot project award or by grants resulting from the IRG pilot project award, or
- Based on other support.

Include all authors, year of publication, title, journal, volume, and page numbers. *Please note: publications based on work supported by the IRG pilot project award that do NOT include acknowledgement of ACS funding may NOT be marked as such.*
TABLE IV.SEVEN YEAR SUMMARY OF SUBSEQUENT GRANTS FOR EACHGRANTEE

List only national competitive grants that have been received and for which the IRG grantee is principal investigator or one of multiple PIs.

In the first two columns, use a check mark to indicate if the grant is:

- A result of the IRG pilot project funding, or
- An unrelated grant.

TABLE V. SEVEN YEAR SUMMARY OF FUNDING

Starting with the most recent year and working backward, please tabulate the percent of applications funded for the past <u>seven</u> years.

TABLE VI. SUMMARY OF ALL PUBLICATIONS AND GRANTS OBTAINED

Going back <u>seven</u> years but excluding awardees currently receiving funding, provide for each individual listed in TABLE I the total number of grants awarded and number of publications as a result of IRG pilot project grant funding. (This is a summary of the information provided in Tables III and IV.)

Provide the numbers of grants and publications obtained by IRG awardees resulting from work unrelated to the IRG award during the same <u>seven-year</u> period. Provide subtotals for each year and an overall total in the space indicated.

15. AWARDEE PROJECTS

Current Pilot Project Grant Applications (up to five pages each)

Please include the applications for pilot project grants for all current (year) awardees. If the provided template is not used, the applications should follow the format of the template, and include a Biographical Information Page(s).

Individual IRG Progress Reports (two to three pages each)

Using the provided template or following its format, please provide progress reports for all pilot projects supported by allocations from the IRG that were completed during the last <u>two</u> years. Pilot project grantees should be instructed to summarize the work accomplished under the grant and the results achieved [NEW: one-page limit]. Include publications and any national grants obtained as a result of IRG funding (i.e., <u>after</u> the pilot project award period).

List the names of all authors, title, journal, and page number for all relevant publications, but do not include manuscripts in preparation. Attach a copy of the publication cover page, including the abstract and acknowledgement of ACS funding for each relevant publication. Information about national grants should include the principal investigator's role, project title, awarding agency, amount of support (direct costs), and the term of the award.

Note: These reports should be updated each year following the IRG pilot project award period, and the revision date noted on the report. The principal investigator will need to collect progress reports from the last <u>seven</u> years of IRG funding, but only those from pilot projects completed in the last <u>two</u> years need to be included in the application.

16. APPLICATION APPENDIX

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

- Examples of how the local IRG Review Committee publicizes the availability of funds;
- Evidence of interaction with the local American Cancer Society; and
- MOU documenting a consortium arrangement with another institution.

Appended materials may also include:

- Letter of support from the American Cancer Society Region, and
- Letters of support from key individuals at the institution.

It is not necessary to number the pages of the Appendix but list the items in the Table of Contents.

APPENDIX A: SAMPLE OF GENERAL AUDIENCE SUMMARY

The American Cancer Society Institutional Research Grant (ACS IRG) is an essential component used by the University to recruit new faculty into cancer research and promote the nurturing for the ideas of junior faculty already involved in cancer research. Over the years, the ACS IRG has successfully fostered cancer interests among young investigators, providing them with a mechanism by which they can obtain small grants for testing their ideas, and positioning them to successfully compete for extramural peer-reviewed research grants.

The leadership of the University, and especially the Comprehensive Cancer Center, understands that new ideas, many of which come from new researchers in their first faculty positions, can have a substantial impact on the advancement of biomedical research. The institution has added a substantial number of junior faculty over the past decade in diverse disciplines that that range from basic molecular biology to psychosocial sciences. This has enlarged the pool of eligible applicants for ACS IRG funding.

In addition, the institutional IRG program has placed increasing emphasis on the identification of potential applicants, which has resulted in a substantial increase in the number of applications. Consequently, the institution's IRG review committee has expanded and diversified.

The present renewal application also includes a new mentoring plan to assure that awardees are properly advised once an award is made and receive training that will help them to secure peer-reviewed funding. Recognizing the importance and prestige of the American Cancer Society Institutional Research Grant for young investigators and to help attract the best young scientists, the University and Cancer Center have committed \$15,000 in matching funds for each ACS IRG pilot project award, bringing the \$30,000 award to \$45,000 per investigator.

The ACS IRG also plays an important role in fostering the extensive interaction between the University and the American Cancer Society. Over the years, this relationship has been mutually beneficial to both organizations, but more importantly to the area's cancer patients and their families.

APPENDIX B: CRITERIA FOR THE REVIEW OF APPLICATIONS

The following items are used by reviewers in evaluating applications for IRGs. Renewal applications must include the critiques of the previous application, and document progress made toward addressing the points made by the reviewers. Resubmitted applications should also include this section. Evaluate the adequacy of the response.

DESCRIPTION OF PROGRAM: This should be an overview of the academic environment and the potential applicant pool size. When describing the nature of the institution, the principal investigator should also outline any unique aspects of the institution. Describe any strategic efforts underway at the institution to expand cancer-related activities, especially research, which could impact faculty recruitment.

Describe the importance of this grant to the institution, with an explanation of how the IRG will be used to leverage resources to support the institution's beginning cancer researchers. If this application is a renewal of an IRG that is no longer in effect, and for which funding has lapsed for more than one year, the PI must provide an explanation.

In the information about the applicant pool, the PI must include the percentage of new faculty annually recruited to the institution, what proportion of these would be potential applicants for IRG pilot project funding, and the overall success rate of junior faculty in obtaining national peer reviewed cancer research funding. Renewal applications should highlight any outstanding accomplishments by the individual awardees. If faculty titles at the institution are different from the standard academic titles, the applicant should explain (e.g., is an "instructor" an independent principal investigator?).

CAREER DEVELOPMENT ACTIVITIES FOR BEGINNING INVESTIGATORS:

Institutions are expected to document activities designed to promote the career development of the recipients of IRG pilot project grants, such as mentoring by established cancer researchers, grant-writing seminars, guidance on developing research collaborations, etc.

LOCAL COMMITTEE COMPOSITION: Are the qualifications of the principal investigator to serve as the committee chair provided? Look for broad representation across all schools and departments from which applications might be expected; a good balance of senior and junior, and clinical and basic researchers, as well as invitations to ACS representatives to participate.

INTERACTION WITH LOCAL ACS: Is there evidence of interaction between the institution, *including IRG pilot project grantees*, and the local Region office of the American Cancer Society or with the ACS Cancer Action Network? For example, are events where the local staff or volunteers get to meet the individual awardees held? If not, has any attempt been made by the institution to nurture such interactions? (In some areas of the country, this is the only funded ACS grant, and special consideration should be given for these interactions.)

PROCEDURE FOR PUBLICIZING AVAILABILITY OF FUNDS: How does the committee advertise—electronic mail, list servers, bulletin boards, campus newsletters, letters to

new faculty? Do all departments and schools know about the grant? Are the numbers of applications commensurate with the pool size?

OPERATIONS (HOW ALLOCATIONS ARE TO BE MADE): The committee's sole charge should be to review the ACS IRG applications, and not any applications funded from other sources. Does the committee meet once or twice each year? How does the committee avoid conflicts of interest? Is there appropriate rotation after several years of service? How are applications ranked? How are special interest applications evaluated? [SUSPENDED] Is there feedback to the applicants?

JUSTIFICATION OF FUNDS REQUESTED: What other cancer research support is available at the institution? Is the projected or actual applicant pool size sufficient to justify the funds requested? If this is a renewal application, does the number of applications agree with the reported pool size? Is the amount requested adequate to fund all the outstanding applications? Conversely, are non-meritorious applications being funded? There should be detailed information about any funds provided by the institution to supplement the pilot project awards or the overall grant.

DOCUMENTATION OF POOL SIZE (*new applications only*): How many junior investigators interested in cancer research are presently at the institution, and how many are expected to be recruited over the next few years? Is this pool sufficient?

EXAMPLES OF RESEARCH TO BE SUPPORTED (*new applications only*): Do the examples of pilot projects reflect high quality cancer research?

APPLICATIONS AND AWARDS: How many applications are received, approved, and funded? What is the funding rate? What is the range of priority scores? Are there enough special interest applications to warrant a special award? *[SUSPENDED]* Are the grantees made aware that this money comes from the ACS rather than the institution? Are pilot project grants distributed broadly across the institution, or concentrated in one school or center?

PUBLICATIONS AND GRANTS: This is an important part of the evaluation of **renewal** requests for continued support. Tracking of publications and awards should go back for <u>seven</u> years (excluding the current year) or the length of the award, if less. Consider the <u>overall</u> productivity of the researchers supported by IRG funds (i.e., all publications and grants, not just those resulting from their IRG pilot projects). *Verify that only those that acknowledge ACS funding are listed*. The cancer relevance of the research supported by individual allocations is also a factor in the evaluation of renewal requests for continued support.

MISSION BOOST GRANT

INSTRUCTIONS

PREPARING THE APPLICATION

1. APPLICATION TEMPLATES

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

2. TABLE OF CONTENTS (PAGE 1.1)

Complete the Table of Contents by indicating the appropriate page numbers for the Research Plan section.

3. BIOGRAPHICAL SKETCH OF APPLICANT (PAGE 2.1)

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

4. RATIONALE AND RESEARCH PLAN (PAGE 3.1)

A. Rationale (500 words or less). What is the clinical need and how will this research program address that need?

B. Research Plan (5 pages or less).

1. Project Status

Briefly summarize the current status of your previously funded ACS project, including resulting publications and funding, and if different, the status of the project you now propose for a Mission Boost Grant.

2. Goals

Briefly describe the research program for the initial phase of MBG funding and the approach(es) that will be taken.

3. Innovation and Opportunity

Describe the expected innovation, major risks, and opportunities of the research program and how they would meet the criteria of high risk/high reward.

4. Milestones

Provide clear, quantitative, and outcome-based milestones for the Primary Boost and describe how accomplishing the outcomes will enable clinical testing in a Secondary Boost. Milestones should not be a restatement of the Aims, but rather a breakdown of how the work will be accomplished and progress monitored.

C. Justification for Secondary Boost (1 page or less)

Provide a brief overview of plans for clinical testing during Secondary Boost. Review of your Secondary Boost application is contingent upon achievement and review of Stage I milestones.

D. References (No page limit)

The list of references should correspond to the citations in the Research Plan. Each literature citation should include the names of all authors, title, book or journal, volume number, page numbers, and year of publication.

7. DETAILED BUDGET

The allowable budget for Stage I of a Mission Boost Grant is \$100,000 in direct costs per year, plus 20% in indirect costs per year, for a maximum term of 2 years. Please complete the budget page located online at proposalCENTRAL.

Personnel. Names and positions of all key personnel must be individually listed, along with the percentage of time each will devote to the project. List all key personnel other than the PI (defined as individuals who will participate actively in the design and/or execution of the studies). Provide details of contractual arrangements with key personnel in the Justification of Budget section of the application.

If an 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, prorated to the salary requested. (For example, if 50 percent of an individual's annual salary is requested, then no more than 50 percent of that individual's annual cost for fringe benefits can be requested.)

<u>Please note:</u>

- For definitions of key personnel refer to Required Information Section in the General Policies.
- Consultants are defined as individuals who will provide any combination of advice, guidance, and reagents and may or may not be considered Key Personnel.
- The Society does not cover the costs of student tuition or fees for graduate or undergraduate students.

B. Equipment.

Permanent equipment. Defined as items of nonexpendable property with a purchase cost per unit of \$5,000 or more, with a useful life of more than one year. List each separately and justify the need for it. Note: the cost of permanent equipment is not included in the direct cost total used to calculate indirect costs.

Small or expendable equipment. Defined as expendable property with a purchase cost per unit of less than \$5,000, and/or that has service life of less than 1 year. Note: the cost of small or expendable equipment may be included in the Direct Cost total used to calculate Indirect Costs.

General purpose equipment. Equipment such as computers or laptops used primarily or exclusively in the actual conduct of the proposed scientific project are considered direct costs and may be included in the Direct Cost total used to calculate Indirect Costs. Computers, laptops, or other general-purpose equipment that will be used on multiple projects or for personal use should not be listed as a direct cost and should not be included in the calculation for indirect cost.

C. Supplies. Group into major categories (glassware, chemicals, radioisotopes, survey materials, animals).

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

E. Miscellaneous Expenditures. List specific amounts for each item; examples of expenditures allowed include publication costs and special fees (e.g. pathology, computer time, scientific software, and equipment maintenance).

F. Subcontracts. If any portion of the proposed research is to be carried out at another institution, enter the total costs (direct) on the online budget detail page on proposalCentral. Then provide a categorical breakdown of costs using the downloadable Subcontractor Budget and Justification form, use one form per subcontractor.

Upload form(s) when complete, entering the subcontractor name in the "describe attachment" box. Note: indirect costs for the subcontract budget may be claimed by either the primary or the secondary institution, but not both.

Subcontracts required to complete the research project may be with public or private institutions if they are not in violation of ACS policies. Subcontracts involving a contractor residing outside the borders of the United States are not permitted unless the applicant can document that it is not feasible to have the work performed within the United States.

Administrative pages: Include a Letter of Agreement pertaining to the subcontract in the Appendix.

G. Indirect Costs. To help the institution provide proper laboratory and clinical facilities, the Society will permit an indirect cost allowance of up to 20% of the direct costs, excluding

permanent equipment. Indirect costs for a subcontract budget may be claimed by either the primary or the secondary institution, but not both. Indirect costs can be provided to the secondary institution through negotiation with the Principal Investigator's institution, but the total amount of indirect costs, inclusive of subcontracts, may not exceed 20% of the award.

H. Total Amount Requested. Budget totals should reflect a maximum duration of 2 years for Stage I (Primary Boost). The total maximum budget may not exceed \$240,000 (direct plus indirect). Enter the sum of all years of requested support, including indirect costs, and round to the nearest thousand dollars. Transfer this figure to the title page of the online application.

8. JUSTIFICATION OF BUDGET

Please provide budget justification on the template provided. Justify all items of permanent equipment costing over \$5,000 and the need for personnel, supplies, travel, and other miscellaneous items. If the budget includes a request for funds to be expended outside the United States or its territories, include an explanation of why such costs are essential for the successful conduct of the project, and why there are no alternatives.

9. BIOGRAPHICAL INFORMATION OF KEY PERSONNEL (PAGE 4.1)

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

10. OTHER SUPPORT (PAGE 5.1)

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

The only exceptions are:

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

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

A. Current Support. List all current funding from intramural and extramural sources (e.g., institutional awards and grants from for-profit and not-for-profit agencies, including other grants from the American Cancer Society). Provide for each award:

a. Source of funds: the organization providing the support

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

Please keep the Scientific Director current on the status of pending applications that have scientific overlap, would interfere with the PI's budgeted effort on the ACS proposal.

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

11. LIST OF LETTERS OF SUPPORT FROM COLLABORATORS/CONSULTANTS (PAGE 6.1)

Provide a list of collaborators and consultants, and then directly upload the letter from each individual collaborator or consultant. The letter should outline the role that person will play with enough detail for evaluation of the value of the individual's contribution.

12. COMPLIANCE STATEMENTS (PAGES 7.1 – 7.3)

Human Subjects

Selection of study population. When conducting research on humans, provide the rationale for selecting your target population. Include the involvement of children, minorities, and especially vulnerable populations such as neonates, pregnant women, prisoners, institutionalized individuals, or others who may be considered vulnerable populations or others who may be considered vulnerable populations of a grant.

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

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

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

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

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

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

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

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

Vertebrate Animals

Provide your rationale for using live vertebrate animals including the:

- 4. Necessity for using the animals and species proposed;
- 5. Appropriateness of the strains, ages, genders of the animals to be used;
- 6. Justifications for, and appropriateness of, the numbers of animals proposed. When completing the Targeted Enrollment Table, select non-human subjects research and check the box that most appropriately describes your research.

<u>Biohazards</u>

Briefly describe whether any materials or procedures proposed are potentially hazardous to research personnel, equipment, and/or the environment. What protections will mitigate such risks? Include biological or chemical hazards.

Authentication of Key Biological and/or Chemical Resources

Briefly describe methods to ensure the identity and validity of key biological and/or chemical resources to be used in the proposed studies. These resources may or may not be generated with ACS funds and:

- may differ from laboratory to laboratory or over time;
- may have qualities and/or qualifications that could influence the research data; and
- must be integral to the proposed research.

These may include, but are not limited to, cell lines, specialty chemicals, antibodies, and other biologics. Researchers should transparently report how they have authenticated key resources, so consensus can emerge.

Standard laboratory reagents that are not expected to vary need not be included in the plan (e.g. buffers and other common biologicals or chemicals). After reviewers assess the information you provide in this Section, their questions will need to be addressed prior to an award. In this section, focus *only* on authentication and/or validation of key resources to be used in the study. Include all other information within the page limits of the research strategy. Applications that fail to comply may be dismissed.

13. APPENDIX TO APPLICATION

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

Appended materials may include:

- Recent reprints or preprints (optional)
- Clinical Protocols (if applicable)

It is not necessary to number the pages of the appendix, but please list by categories (e.g., reprints, preprints) in the table of contents of the application.

APPENDIX A: REVIEWER GUIDELINE CRITERIA

PART I Candidate

Investigator:

Provide an overall evaluation of the candidate's academic, clinical, and/or scientific qualifications, their potential for continued success as an independent investigator, and their continued commitment to a career in cancer-related research. Assess the qualifications of the applicant considering the following items: goals and commitment to cancer-related research; productivity, support, collaborators and appropriateness of the candidate for the MBG.

PART II Research plan and Milestones

It is critical to evaluate rather than summarize the research plan and milestones. The research plan must be fundamentally sound, innovative and reduce the risks of studying a new drug, device, or procedure in patients. In critiquing the research plan, please be as specific and as detailed as possible about the following elements:

1. Status of the previously funded project

While the Mission Boost need not be related to prior ACS funding, applicants should show productivity from prior ACS investment.

2. Goals and Rationale

Does the project address an important clinical problem or a critical barrier to clinical progress? If the aims of the project are achieved, how will clinical practice improve? How will successful completion of the aims change clinical practice?

3. Innovation and Opportunity

Is the proposed research innovative? Mission Boost Grants are high risk/high reward endeavors. Are the expected risks worth the potential opportunity? What is the potential that the proposed study will challenge and seek to shift current clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, or instrumentation? Does the research propose meaningful improvements or address critical gaps?

4. Approach

Will the planned approaches accomplish the project goals? Are study design, methods for implementation, data collection and analysis appropriate for answering the research question? Where appropriate, are proposed recruitment and/or case ascertainment methods well developed? Is the sample size adequate? Is the research timeline realistic?

5. Milestones

Will accomplishing the milestones enable clinical testing in a secondary MBG?

6. Investigator/Research Team

Does the PI and research team have the training and experience needed to carry out the proposed research? Do team members have complementary skills and qualifications needed for successful implementation and analysis of the proposed research?

PART III JUSTIFICATION FOR SECONDARY BOOST

Evaluate the overall justification for the secondary boost. Will accomplishing the goals of the primary boost enable clinical testing in the secondary boost?

PART IV BUDGET

Evaluate the budget for the primary boost. Are the budget items justified, specified, and accurate? Is the project duration and the percent effort of key personnel appropriate? Is there a potential overlap with the PI's other funded research? Describe any suggested budget changes - use specific amounts or percentages.

It is the policy of the American Cancer Society not to fund projects that are supported all or in part by another agency.

PART IV COMPLIANCE STATEMENTS

1. Human Subjects. If applicable, evaluate the plans for protection of human subjects from research risks justified in terms of the scientific goals and research strategy proposed. For example, are the potential benefits & risks to subjects articulated reasonable and appropriate given the study design? Are their plans for conducting sub-analysis by group, data security and confidentiality, biohazards and data and safety monitoring adequate.

2. Inclusion of Women, Minorities, and Children. When the proposed project involves human subjects, evaluate the adequacy of the proposed plans for inclusion or exclusion of minorities, male and female genders, as well as children.

3. Vertebrate Animals. Evaluate the plan for live, vertebrate animals as part of the scientific assessment according to the following points: 1) necessity for the use of the animals and species proposed; 2) appropriateness of the strains, ages, and gender; 3) justifications for, and appropriateness of, the numbers of animals.

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

CLINICIAN SCIENTIST DEVELOPMENT GRANT

INSTRUCTIONS

PREPARING THE APPLICATION

PART I – ADMINISTRATIVE INFORMATION, CANDIDATE, RESEARCH PLAN AND BUDGET

1. COVER PAGE

Program Eligibility Information. Most of the information collected online at proposalCENTRAL appears on the cover page. This includes program eligibility information: (1) Last degree conferred and (2) Independent position date. This information *is required* to determine eligibility for a **Clinician Scientist Development Grant** (CSDG). If you requested and have received a letter from the American Cancer Society Eligibility Committee, *manually* indicate this on the cover page in the Program Eligibility Information section and attach the letter in the Appendix.

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

2. APPLICATION TEMPLATES

An application consists of several sections that must be downloaded, completed offline, and uploaded before the online application is submitted. Once an application is started on ProposalCENTRAL, all necessary application templates are available to download. Complete off-line (instructions described in individual sections below) and upload as .pdf documents before submitting the online application. *For assistance, see proposalCENTRAL's FAQ or call support at 1-800-875-2562.*

3. TABLE OF CONTENTS (PAGE 1.1)

Complete the Table of Contents by indicating the appropriate page numbers for each section. **Note: limit the length to two pages.**

4. STATEMENT OF EXPERIENCE AND CAREER GOALS OF THE APPLICANT (PAGE 2.1)

In three pages or less, describe:

- A. Clinical and research experiences that have been impactful and why. For all research experience, state the nature, results, location, time frame, with whom the work was conducted, and your role;
- B. The training potential of the fellowship beyond graduate work. Include new technical and conceptual approaches the training will offer;
- C. Short- and long-term career goals in cancer research and how the proposed training and research plans align with these goals.

5. BIOSKETCH OF THE APPLICANT (PAGE 3.1)

Complete the NIH Biosketch template, following the format and instructions provided by the NIH. **Note: The Biographical Sketch may not exceed five pages.**

6. LIST OF RECOMMENDERS (PAGE 4.1)

List the name, title, and email address of three persons, other than your proposed mentor(s), who can critically appraise your qualifications. Also provide this contact information on proposalCENTRAL so that they can access the site to upload their letters.

They should be able to comment on your character, motivation, maturity, general knowledge, ability to use research techniques, originality, specialized experience, and training.

There are specific instructions on the site for you and your recommenders. Your application cannot be submitted until these letters have been provided on proposalCENTRAL.

Please Note for Resubmissions Only: Letters of recommendation can be reused in a resubmission if the application is resubmitted within a calendar year of the initial proposal. Your recommenders *are required to upload the letters to proposalCENTRAL again*.

7. REPLY TO PREVIOUS REVIEW (RESUBMISSIONS ONLY) (PAGE 5.1)

IF YOUR APPLICATION IS A NEW SUBMISSION, upload this template with "Not Applicable" in the body.

All resubmissions must create a new application on proposalCENTRAL. For

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

8. PREVIOUS CRITIQUES (RESUBMISSIONS ONLY)

Electronic copies of the critiques for your previous submission can be downloaded from your "Submitted" page on proposalCENTRAL. Select the links to "View Review Info," then "View Summary Statement," and save the document to your computer. Upload the document to your new application following the Reply to Previous Review section.

9 A. RESEARCH PLAN AND ENVIRONMENT (PAGE 6.1)

Please note: applicants to the **Priority Area Focused on Cancer Health Equity** should use Research Plan 9B. (below).

The total length of the RESEARCH PLAN section should not exceed 13 pages. Section A below (Specific Aims) should not exceed one page. Sections (B) through (E) below must not exceed 12 pages. This page limit does not include Sections (F) through (J).

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

- **A. Specific Aims (one page):** List the objectives, and goals of your proposed research and briefly describe the specific aims.
- **B.** Background and Significance: Concisely summarize and critically evaluate relevant work done by others. Specifically state how your successful completion of the proposed work will advance scientific knowledge or aspects of clinical practice that are important for a better understanding of cancer, control of cancer, or management of cancer patients.

C. Innovation:

- 1. If applicable, explain how the application challenges and seeks to shift current research or clinical practice paradigms.
- 2. Describe any novel theoretical concepts, approaches, methodologies, instrumentation, or intervention(s) you propose to develop or use, and any advantages or advances they offer over existing ones.
- 3. Explain any refinements, improvements, or new applications of theoretical concepts, approaches, methodologies, instrumentation, or interventions.
- **D. Preliminary Studies:** Provide results of your prior research, if any, that are relevant to this proposal; reprints or preprints may be included in the Appendix. *Note* that the entire application is considered confidential.
- E. Research Design and Methods: Describe your overall hypothesis, proposed methods, procedures, and plan for data collection and analysis in sufficient detail to permit evaluation by other scientists. Include your rationale for approaches and analysis. Explain your project's feasibility and how the proposed research will address the Specific Aims. Discuss potential difficulties and limitations of your proposed methods and provide alternative approaches. Inclusion of a study timeline can be helpful. 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.

- **F.** Experimental Details (optional not to exceed three pages): This section is available if more in-depth descriptions of the experimental design, technologies, or assays are needed to convey the specific approaches and procedures proposed.
- **G. Environment for Research and Training:** Document the existence of an appropriate academic and research environment for the proposed research study and training program, including:
 - departmental and other institutional personnel,
 - ongoing research and other relevant activities,
 - facilities and resources,
 - access to any populations or individuals to be studied,
 - relevant collaborative relationships, and
 - any relevant accreditation from professional societies or organizations.

Describe how the presence of these resources will directly benefit you and your research.

- H. Statement of Cancer Relevance (limit to 250 words): This section is important to stakeholders (non-scientific members) on the peer review committees as well as several general audiences, including donors. Avoid the use of technical jargon. Describe the short-and long-term contributions the proposed work will have on the control of cancer. For basic studies relying on experimental models (rather than human cancer cells, tissues, or clinical data), explain how the successful completion of the proposed work will lead to a better understanding of the disease, or improve our ability to prevent, detect, treat or manage cancer or cancer patients. For studies involving human subjects, what do you expect to learn about how access to care impacts the overall cancer burden? How could your study improve both the delivery of care or cancer outcomes? What effects do you anticipate on the morbidity, mortality, and/or quality of life of your study population? How might further investigations find potential value for health policy or public health?
- I. Statement of Science Outreach and Advocacy (not to exceed one page): The ACS considers it important that scientists communicate the results of their research to a wide range of communities. Explain the potential impact of your proposed project on your community, and to the ACS's mission of eliminating cancer as a major health problem. Share any previous experiences in science outreach and advocacy. Describe your plans for disseminating your work in the cancer arena through advocacy, awareness, education, or service. Please include your plans for sharing your research and research findings with your (non-academic) community members and for engaging with community partners in the dissemination process.

J. References (no page limit): Each literature citation should include the title, authors, book or journal, volume number, page numbers, and year of publication. This section is not included in the 12-page limit of Sections (B) through (F).

9 B. RESEARCH PLAN AND ENVIRONMENT -

Use this outline if you are applying to the Priority Area Focused on Cancer Health Equity.

Definitions and Key Words

ACS Cancer Health Equity definition: Cancer health equity involves everyone having a fair and just opportunity to prevent, detect, treat, and survive cancer. Health inequities and health disparities may be characterized by age, gender, disability status, ethnicity/race, nativity and immigration status, geography, income, language, social class and sexual orientation.

Social Determinants of Health: This refers to macro-environmental conditions where people are born, grow, live, work, and age along with the available systems supporting health. Research may include aspects of the following domains of the social determinants of health inequities: economic; education; neighborhood and built environment; policy; social and community context; or factors impacting access to and provision of high-quality care.

Levels of Influence: individual, interpersonal, organizational, community, or public policy.

All cancer health equity applications must target two or more determinants of health.

The total length of the RESEARCH PLAN section should not exceed 13 pages. Section A below (Specific Aims) should not exceed one page. Sections (B) through (E) below must not exceed 12 pages. This page limit does not include Sections (F) through (J).

- A. Specific Aims (1 page): List the objectives and goal(s) of the research proposed. Briefly describe the Specific Aims in the context of two or more of the social determinants of health for which your proposed research will contribute to achieving health equity.
- **B.** Background and Significance: Concisely summarize and critically evaluate work pertaining to social determinants of health and cancer health equity topics, which will be the focus of your research. State how successful completion of the proposed work will advance cancer health equity related to some aspect of the cancer control continuum: prevention, screening and early detection, diagnosis, treatment, palliative care, or survivorship.

C. Innovation:

- 1. If applicable, explain how the application challenges and seeks to shift current social, political, research, or clinical practice paradigms in relation to health equity.
- 2. Describe any novel theoretical concepts, approaches, methodologies, technologies, or intervention(s) to be developed or used, and any advantage over existing methodologies, or intervention(s) addressing cancer health equity.

- 3. Explain any refinements, improvements, or new applications of theoretical concepts, models, methodologies, technologies, or interventions.
- 4. If applicable, explain what is unique in your approach to address an important issue regarding the social determinants of health and cancer health equity. Describe how this innovation may be enhanced by community, health systems, or public policy partnerships.
- **D. Preliminary Studies:** Provide results of your prior research that are relevant to this proposal; reprints or preprints may be included in the Appendix. *Note* that the entire application is considered confidential.
- **E. Research Design and Methods:** Describe your overall hypothesis, proposed methods, procedures, and plan for data collection and analysis in enough detail to permit evaluation by other scientists; include your rationale for approaches and analysis. Explain your project's feasibility and how the strategies proposed will address the Specific Aims. Discuss potential difficulties and limitations of your proposed methods and provide alternative approaches. Inclusion of an experimental time-line can be helpful.

All cancer health equity applications must address two or more social determinants of health in relation to the following domains: economic; education; neighborhood and built environment; policy; social and community context; or factors impacting access to and provision of high-quality care. Applicants proposing multi-level health equity research must also target two or more levels of influence (individual, interpersonal, organizational, community, or public policy) and focus on contributing to achieving health equity. Applicants are at liberty to use more than one model to describe the theoretical underpinning of their research approach.

- **F.** Potential for Knowledge Transfer and Experimental Details (Three pages or less): Create a clearly defined plan of how the results of the study will be used to develop future research and how it will practically impact cancer health equity. Concisely describe how the findings will be disseminated. Describe potential application of study findings to the work of ACS. This section is also available if more in-depth description of the study design, technologies, or other aspects are needed to convey the specific approaches and procedures proposed.
- **G.** Environment for Research and Training: Document the existence of an appropriate academic and research environment for the proposed research study and training program, including:
 - departmental and other institutional personnel,
 - ongoing research and other relevant activities,
 - facilities and resources,
 - access to any populations or individuals to be studied,
 - relevant collaborative relationships, and

• any relevant accreditation from professional societies or organizations.

Describe how the presence of these resources will directly benefit you and your research.

- **H. Statement of Cancer Relevance (not exceed 250 words):** This section is important to stakeholders (non-scientific members) on the peer review committees as well as to several general audiences, including donors. Avoid technical jargon. Describe the short- and long-term contributions to the control of cancer in the context of cancer health equity. What do you expect to learn about how the social determinants of health impact the overall cancer burden? How could your study inform improvements in equitable access to care and preventive services; the delivery of care; or cancer outcomes? What effects do you anticipate your findings will have on understanding or addressing inequities in morbidity, mortality, and/or quality of life of your study population? How might your findings inform health policy or public health?
- I. Statement of Science Outreach and Advocacy (not to exceed one page): The ACS considers it important that scientists communicate the results of their research to a wide range of communities. Explain the potential impact of your proposed project on your community, and to the ACS's mission of eliminating cancer as a major health problem. Share any previous experiences in science outreach and advocacy. Describe your plans for disseminating your work in the cancer arena through advocacy, awareness, education, or service. Please include your plans for sharing your research and research findings with your (non-academic) community members and for engaging with community partners in the dissemination process.
- J. References (no page limit): The list of references should correspond to the citations under headings A-G above. Each literature citation should include the title, authors, book or journal, volume number, page numbers, and year of publication. This section is not included in the 12-page limit of Sections (B) through (F).

10. DETAILED BUDGET

Please complete the budget page located online at proposalCENTRAL

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

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

For each study team member, indicate the proposed percent effort and the salary and fringe benefits for which the total requested salary is based. The costs to the institution of employee fringe benefits should be indicated as a percent of the employee's salary. The amount of fringe benefits requested must be prorated to the salary requested. (For example, if 50 percent of an individual's annual salary is requested, then no more than 50 percent of that individual's annual cost for fringe benefits can be requested.)

Note: For definitions of Key Personnel refer to General Policies - Required Information.

List all mentor(s), defined as those individuals who will provide guidance, support and mentoring to you on this award.

Mentor(s): \$10,000 per year is the maximum allowable for mentor(s), regardless of the number of mentors on the application.

B. Equipment:

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

Small or expendable equipment: defined as expendable property with a purchase cost per unit that is less than \$5,000 and/or has a short service life (<1 year). *Note:* the cost of small or expendable equipment may be included in the Direct Cost total used to calculate Indirect Costs.

General purpose equipment: Equipment such as computers or laptops used primarily or exclusively in the actual conduct of the proposed scientific project are considered direct cost and may be included in the Direct Cost total used to calculate Indirect Costs. Computers, laptops or other general-purpose equipment that will be used on multiple projects or for personal use should not be listed as a direct cost and should not be included in the calculation for indirect cost.

C. Supplies: Group into major categories (e.g. glassware, chemicals, radioisotopes, survey materials, animals).

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

Please include funds (approximately \$1,500 per year) for the PI to travel to national meetings and conferences. During your project period, you may be invited to attend the Katherine M. Foley Palliative Care and Research Symposium Retreat or an ACS-related conference. These funds will be expected to be used to attend these invited meetings. For years where when you are not invited to attend these meeting, funds may be used to attend other national meetings and conferences to present your research and/or to stay abreast of scientific updates in your field.

E. Miscellaneous Expenditures: List specific amounts for each item. Examples of allowed expenditures include: publication costs and special fees (e.g., pathology, computer time, scientific software, and equipment maintenance).

F. Subcontracts: If any portion of the proposed research is to be carried out at another institution, enter the total costs (direct) on the online budget detail page on proposalCENTRAL. Then provide a categorical breakdown of costs using the Subcontractor Budget and Justification form, using one form per subcontractor. Upload the form(s) when complete, entering the subcontractor's name in the "describe attachment" field. **Note:** indirect costs for the subcontract budget may be claimed by either the primary or the secondary institution, but not both.

Subcontracts for the research project may be with public or private institutions, provided they do not violate ACS policies. Subcontracts involving a contractor residing outside the borders of the United States are not permitted, unless the applicant can document that it is not feasible to have the work performed within the United States.

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

G. Indirect Cost: To help the institution provide proper laboratory and clinical facilities, the Society will permit an indirect cost allowance of up to 8% of the direct costs, excluding permanent equipment. Indirect costs can be provided to the secondary institution through negotiation with the Principal Investigator's institution but the total amount of indirect costs, inclusive of subcontracts, may not exceed 8% of the award.

H. Total Amount Requested: Budget totals should reflect a duration of 3-5 years (see table below). The allowable per year direct cost is \$135,000 per year and the indirect cost rate is 8% (\$10,080 max), making the total cost per year cap \$145,800. Personnel costs are included in the direct cost per year cap of \$135,000.

The Society and its peer review committees expect applicants to show judicious use of proposed funds in all grant applications. Enter the sum of all years of requested support, including indirect costs, and round to the nearest thousand dollars. Transfer this figure to the title page of the online application.

11. JUSTIFICATION OF BUDGET

Please provide budget justification on the template provided.

Clearly justify each item listed in the budget. This includes all permanent equipment costing over \$5,000, personnel, supplies, travel, and other miscellaneous items. If the budget includes a request for funds to be expended outside the United States or its territories, this section should include an explanation of why such costs are essential for the successful conduct for this project, and why there are no alternatives. Provide details of contractual arrangements with key personnel in this section.

Additional Mentors: If there is more than one mentor on the application, clearly specify the role of each mentor, even if there is no associated cost.

12. BIOGRAPHICAL INFORMATION OF KEY PERSONNEL (PAGE 7.1)

Complete the NIH Biosketch template. *Note:* Follow the format and instructions provided by the NIH. This is a required field. Therefore, if no Key Personnel are included, a blank form must be uploaded. Do not include the Mentor's biosketch in this section.

13. OTHER SUPPORT (PAGE 8.1)

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

The only exceptions are:

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

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

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

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

Please keep the Scientific Director current on the status of pending applications that have scientific overlap, would interfere with the PI's budgeted effort on the ACS proposal, or could compromise CSDG eligibility (i.e., more than one R01 or R01-like grant as PI at the time of application).

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

These details should be confirmed by the Department Chair in the Statement of Institutional Support included in Section 14, below.

Non-tenure track applicants should also include a more detailed description of the space committed to the project. If the applicant is in the same department as a previous mentor, provide information on the relationship between the mentor's research space, and the space available for the project, and the relationship between funded research projects in the mentor's laboratory and the present application. Documentation should be included in the Statement of Institutional Support (Section 14, below) written by the Department Chair.

PART II - TRAINING AND MENTORING PLAN

The following sections must be prepared by the proposed *primary mentor*. Use the templates provided.

14. FACULTY OR SCIENTIFIC APPOINTMENT (OF CANDIDATE) (PAGE 9.1)

A letter from the Department Chair (or equivalent) must be included in the application (upload in this section). This letter should clearly indicate the commitment of the institution to the support of the applicant and their research program. Details should include, but are not limited to, faculty rank, salary support, available space for the research proposal, and the amount of protected time for clinical researchers. The letter should also describe the Department's long-term goals for the applicant's career (see Section 13. Other Support (3) Institutional Support for additional information that should be included in this letter.)

15. PROGRAM GOALS AND PROPOSED TRAINING (PAGE 10.1)

Describe the overall goals of the proposed program and indicate how the grant, if awarded, will advance the candidate's career as an independent researcher. Provide a description of the specific plans for research training, including core curriculum studies, courses and lectures. For each mentor, describe their role, area of expertise, and the frequency and mode of contact with the Candidate should be provided. Explain in detail the activities planned for the period of the award, including clinical, research, teaching, coursework, administrative duties, etc., and skills the candidate will gain from the mentoring experience. Estimate the percentage of time allocated to each area. The primary mentor is expected to compose the mentoring and training plan. If an additional mentor is involved in the candidate's training, describe this person's participation as well. Include a table indicating the timeline of implementation and completion of the Training Plan.

16. TRAINING EXPERIENCE OF MENTOR(S) (PAGE 11.1)

Document your background and experience in training clinical and applied cancer researchers. Describe *in detail* (table format preferred) your mentoring experience (e.g., list the researchers you have trained, the extent of their training, and their current involvement in clinical or applied cancer research). Fully describe your current professional responsibilities and activities.

17. BIOGRAPHICAL SKETCH OF MENTOR(S) (PAGE 12.1)

Provide biographical information requested for *all mentors*. Complete the NIH Biosketch template. Follow the format and instructions provided by the NIH. Use a separate "Biographical sketch" template for each mentor. *Note:* The Biographical Sketch may not exceed five pages.

18. MENTOR(S) COMMITMENT LETTER(S) (PAGE 13.1)

A letter of commitment must be provided from each mentor. The letter should include assessment of the Candidate's research ability and potential, motivation, ability to plan and conduct research, knowledge of the field of study, and ability to work as a member of a research team. Letters may also include other attributes of the Candidate such as character or motivation. The letters will need to be uploaded as an attachment to your application

SECTION III - COMPLIANCE STATEMENTS

19. COMPLIANCE STATEMENTS (PAGE 14.1)

Human Subjects:

Selection of study population: When conducting research on humans, provide the rationale for selection of your target population including the involvement of children, minorities, special vulnerable populations, such as, neonates, pregnant women, prisoners, institutionalized individuals, or others who may be considered vulnerable populations*. This should include research subject gender and the rationale for why certain populations may be excluded based on your research question and specific aims. Complete the planned enrollment form based on your proposed study sample size to estimate the total number of subjects by primary ethnicity and race, race/ethnicity subgroup (if applicable) and gender. Also include estimates of the sample distribution by gender and race and ethnicity (if available). For example, if your sample size is 200, to complete the total number for the subjects' column by race (based on what you know about the population demographics or the existing dataset you plan to analyze) multiple by the estimated percentage.

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

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

Potential benefits and risks and knowledge gained: Succinctly describe the potential benefits and risks to subjects (physical, psychological, financial, legal, or other). Additionally, provide

justification for why potential risks to subjects are reasonable in relation to the anticipated benefits to research participants and others. Where appropriate, describe alternative treatments and procedures, including the risks and potential benefits of the alternative treatments and procedures, to participants in the proposed research.

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

Collaborating sites:

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

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

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

Vertebrate Animals:

Provide the rationale for inclusion of live vertebrate animals according to the 1) necessity for the use of the animals and species proposed; 2) appropriateness of the strains, ages, and gender of the animals to be used for the experimental plan proposed; and 3) justifications for, and appropriateness of, the numbers used for the experimental plan proposed. When completing the Targeted Enrollment Table select non-human subjects' research and check the box that most appropriately describes your research.

<u>Biohazards:</u>

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

Authentication of Key Biological and/or Chemical Resources:

Briefly describe methods to ensure the identity and validity of key biological and/or chemical resources used in the proposed studies.

Key biological and/or chemical resources may or may not be generated with ACS funds and:

- 1. may differ from laboratory to laboratory or over time;
- 2. may have qualities and/or qualifications that could influence the research data; and

3. are integral to the proposed research.

These include, but are not limited to, cell lines, specialty chemicals, antibodies, and other biologics. Researchers should transparently report on what they have done to authenticate key resources, so that consensus can emerge.

Standard laboratory reagents that are not expected to vary do not need to be included in the plan. Examples are buffers and other common biologicals or chemicals.

Reviewers will assess the information provided in this Section. Any reviewer questions associated with key biological and/or chemical resource authentication will need to be addressed prior to award.

Information in this section must focus only on authentication and/or validation of key resources to be used in the study; all other methods and preliminary data must be included within the page limits of the research strategy. Applications identified as non-compliant with this limitation may be withdrawn from the review process

<u>Priority Focus in Health Equity Research on the Cancer Prevention and Control Research</u> <u>Grants Program: Cancer Health Equity Statement (750 words limit)</u>

Applicants proposing health equity research must upload a Cancer Prevention and Control Health Equity Statement (Page 8.3). Summarize the targeted area(s) of health equity, the study population, and how the proposed research is anticipated to contribute to improving health equity relevant to cancer. Describe how your anticipated findings will advance the field. This must pertain to an aspect of the cancer continuum and two or more of the social determinants of health.

Examples of research in this area include, but are not limited to, projects that result in improvements in:

- risk reduction behaviors;
- access to cancer prevention;
- early detection, diagnosis, and/or treatment services;
- reducing cancer morbidity, mortality, symptom burden, or costs; and
- quality of care, quality of life, addressing structural barriers, or health policy impact.

20. APPENDIX TO APPLICATION

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

Appended materials may include:

• Letter from ACS Eligibility Committee confirming eligibility (if applicable)

- Letters of support
- Recent reprints or preprints (optional)
- Clinical Protocols (if applicable)
- Logic Model (for program projects and dissemination and implementation pilots if applicable)

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

APPENDIX A: REVIEW CRITERIA

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

PART I - CANDIDATE, RESEARCH PLAN, AND BUDGET

Section 1. Items for Evaluation of Candidate

Describe the qualifications of the applicant considering the following items: goals and commitment to cancer research; past education; past training – board eligible or board certified, if appropriate; past research experience; number and relevance of previous publications; and overall appropriateness of candidate for the CSDG. Assess whether the proposed research career and development plans broadens the training and experience of the applicant beyond what was obtained in their graduate work and aligns with the applicant's stated career goals.

Letters of Recommendation:

Summarize and provide an assessment of letter contents. Please place your comments at the end of your critique so this section can be deleted to maintain strict confidentiality. Letters of recommendation should indicate the applicant's research ability and potential, ability to plan and conduct research, his/her knowledge of the field of study relevant to the proposed research, and ability to work as a member of the research team. Letters of recommendation should also allow an assessment of personal characteristics, e.g., character and motivation.

Section 2. Items for evaluation of Research Plan

REPLY TO PREVIOUS REVIEWS [IF APPLICABLE]

Note whether this is a resubmission and comment on adequacy of response to critiques.

Research Plan:

A junior investigator's research is not expected to reflect the breadth and depth of a senior scientist's approach. Nevertheless, the research plan must be fundamentally sound. In critiquing the research study, please be as specific and as detailed as possible about the following elements:

1. Significance: Does the project address an important problem or a critical barrier to progress in the field? If the aims of the project are achieved, how will scientific knowledge, technical capabilities, and/or clinical practice improve? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or interventions that drive this field? If health equity research is proposed, is it clear which social determinants of health (two or more) are the focus of the proposed research and how the findings may contribute to achieving health equity?

2. Innovation/Improvement: What is the potential that the proposed study will challenge and seek to shift current research understanding or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the

concepts, approaches or methodologies, instrumentation, or interventions? Does the research propose meaningful improvements or address critical gaps?

3. Investigator/Research Team or Candidate/Mentoring Team: Does the PI, mentoring and research team have the training and experience needed to carry out the proposed research? Do team members have complementary skills and qualifications needed for successful implementation and analysis of the proposed research? Has the research team previously collaborated on research or publications? If not, are members of the proposed study team appropriate to carry-out the research?

4. Approach: Are the study design, methods of implementation, and data collection and analysis appropriate for answering the research question(s)? Where appropriate, are proposed recruitment and/or case ascertainment methods well developed? Is the sample size adequate? Is the research timeline realistic? Are potential pitfalls, alternative approaches, and future plans articulated?

5. Environment: Will the scientific environment and institutional support contribute to the probability of success? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

6. Cancer Relevance: How is this research relevant or how will it benefit persons at risk for, or living with cancer and their family / caregivers? The relevance to cancer may be indirect, but the connection must be clearly articulated by the applicant.

7. Statement of Science Outreach and Advocacy (Feedback optional; this section should not be included in consideration of scoring): Does the outreach and advocacy plan present any concerns (including, but not limited to, research compliance, participant safety, and/or feasibility)? Do you have any suggestions to improve the plan?

Section 3. Items for evaluation of the Budget and Justification of Budget

BUDGET

Evaluate the overall budget and individual budget categories with respect to the award cap and the project aims, mentoring plan, and training plan. Are the budgeted items justified, specified, and accurate? Is the project duration and percentage effort of key personnel appropriate, including PI percent effort (minimum of 50%)? If the PI's effort is not budgeted at 50%, are details provided to explain how the remaining percent will be supported, i.e., start-up funds, department chair's budget, etc. Is there a potential overlap with the PI's other funded research? Describe any suggested budget reductions - use specific amounts or percentages. It is the policy of the American Cancer Society not to fund projects that are supported totally or in part by another agency.

PART II – TRAINING AND MENTORING PLAN

Section 4. Items for evaluation of the Training and Mentoring Plan

REVIEW OF THE TRAINING PLAN A. PROGRAM GOALS AND PROPOSED TRAINING Comment on 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.

B. INSTITUTIONAL RESOURCES AND ENVIRONMENT FOR TRAINING

Assess the suitability of the academic and research environment for the proposed training program. Consider 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. Assess whether the presence of these resources will directly benefit the candidate.

REVIEW OF MENTORING PLAN

C. QUALIFICATIONS AND TRAINING EXPERIENCE OF MENTOR(S):

1. Qualification of Mentor(s). Evaluate the appropriateness of the mentor's (mentors') experience for their respective roles in the proposed training and mentoring plan. Consider the faculty or scientific appointment, reputation of the mentor(s) in cancer research, history of experience and success in fostering the development of cancer researchers, productive and current level of research funding.

2. Role and Mentor(s) Letters of Support. Evaluate the role and commitment of the mentor(s) to the plan, e.g., percentage of time available for supervision of the candidate, skills or other unique contributions of the mentor to the candidate, any additional resources (such as startup funds) being made available to candidate, and overall appropriateness of mentor(s).

SECTION III: COMPLIANCE STATEMENTS:

1. Human Subjects. If applicable, evaluate the plans for protection of human subjects from research risks justified in terms of the scientific goals and research strategy proposed? For example, are the potential benefits and risks to subjects articulated reasonable and appropriate given the study design? Are there plans to conduct sub-analysis by group, data security and confidentiality, biohazards and data and safety monitoring (if applicable) adequate.

2. Inclusion of Women, Minorities, and Children. When the proposed project involves human subjects, evaluate the adequacy of the proposed plans for inclusion or exclusion of minorities, male and female genders, as well as children.

3. Vertebrate Animals. Evaluate the plan for live, vertebrate animals as part of the scientific assessment according to the following points: 1) necessity for the use of the animals and species proposed; 2) appropriateness of the strains, ages, and gender; 3) justifications for, and appropriateness of, the numbers of animals.

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

Priority Focus on Health Equity Research in The Cancer Prevention and Control Research Grants Program: Cancer Health Equity Statement (750 words maximum)

Applicants proposing health equity research must upload a Cancer Prevention and Control Health Equity Statement (8.3) which summarize the following: targeted area(s) of health equity, study population, social determinants of health of interest (≥ 2) and how the proposed research can contribute to improving health equity relevant to cancer

POSTDOCTORAL FELLOWSHIP

INSTRUCTIONS

PREPARING THE APPLICATION

PART I - CANDIDATE

COVER PAGES

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

1. APPLICATION TEMPLATES

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

2. TABLE OF CONTENTS (PAGE 1.1)

Indicate the appropriate page number for the start of each section. At the bottom of the template, list the documents in the appendices. Section must not exceed two pages.

3. BUDGET

Please complete the budget page located online at proposalCENTRAL. Stipends for Postdoctoral Fellowships are \$52,000, \$54,000, and \$56,000 for the first, second, and third years respectively. Fellows eligible for only two years may request progressive stipends of \$54,000 and \$56,000, respectively. **One-year fellowships are no longer offered but resubmissions of 1-year fellowships are grandfathered in and a request of \$56,000 is allowed.**

Each fellow will receive a **yearly allowance of \$4,000** to be used to benefit the fellow (i.e., health insurance, workshop costs, travel to scientific meetings, etc.). In the last year of funding, a \$1,500 **travel allowance** is to be prioritized for travel costs to attend the biennial ACS Jiler Professors and Fellows Conference, if offered that year, or travel to a domestic scientific meeting of choice. **Institutional indirect costs may not be recovered from these funds.**
4. PENDING FELLOWSHIP APPLICATIONS (PAGE 2.1)

List all sources of **current** and **pending** fellowship support with other funding agencies. Indicate the granting agency, start date, and full term of the award.

5. BIOGRAPHICAL SKETCH OF APPLICANT (PAGE 3.1)

Complete the NIH Biosketch template, following the formats and instructions as provided by the NIH.

6. REPLY TO PREVIOUS REVIEW (PAGE 4.1)

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

All resubmissions must create a new application on proposalCENTRAL.

For Resubmissions:

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

7. PREVIOUS CRITIQUES (RESUBMISSIONS ONLY)

Previous critiques must be included with resubmissions. This will sequentially involve downloading from your "Submitted" page on proposalCENTRAL, selecting "View Review Info," selecting "View Summary Statement," saving the document to your computer, and then uploading the document along with the other proposal sections prior to online submission.

8. STATEMENT OF EXPERIENCE, TRAINING POTENTIAL OF THIS FELLOWSHIP, AND CAREER GOALS OF APPLICANT (PAGE 5.1)

In three pages or less, describe:

- A. Research experiences that have been impactful and why;
- B. The training potential of the fellowship beyond graduate work. Include new

technical and conceptual approaches the training will offer;

C. Career goals in cancer research and how the proposed training and research plans align with these goals.

9. PLANS FOR WORK UNDER FELLOWSHIP (PAGE 6.1)

A. Research Plan: The total length of this section should not exceed nine pages, <u>excluding</u> references. Proposals should be realistic in terms of work to be accomplished in the time period for which support is requested. Failure to conform to the guidelines on type size, page length, or project scope will result in the application being returned to the investigator without review. All cancer health equity applications must target two or more determinants of health. Applicants are at liberty to include a narrative describing the theoretical unpinning of the research plan using one or more theoretical models. For resubmission of a previous application, see Section 6.

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

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

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

HEALTH EQUITY RESEARCH PLAN- use this outline if you are applying to the Priority Area Focused on Cancer Health Equity

Definitions and Key Words

ACS Cancer Health Equity Definition: Cancer health equity involves everyone having the fair and just opportunity to prevent, detect, treat, and survive cancer. Health inequities and health disparities may be characterized by age, gender, disability status, ethnicity/race, nativity and immigration status, geography, income, language, social class and sexual orientation.

Social Determinants of Health: This refers to macro-environmental conditions where people are born, grow, live, work and age along with the available systems supporting health. Research may include aspects of the following domains of the social determinants of health inequities: economic; education; neighborhood and built environment; policy; social and community context; or factors impacting access to and provision of high-quality care.

A. Research Plan: The total length of this section should not exceed nine pages, <u>excluding</u> references. Proposals should be realistic in terms of work to be accomplished in the time period for which support is requested. Failure to conform to the guidelines on type size, page length, or project scope will result in the application being returned to the investigator without review.

- I. Specific Aims: List the objectives and goal of the research proposed and describe the specific aims briefly in order of priority and in the context of two or more of the social determinants of health your research will address to contribute to achieving health equity.
- II. Background and Significance: Concisely summarize and critically evaluate related work pertaining to social determinants of health and cancer health equity topics, which will be the focus of your research. State how successful completion of the proposed work will advance cancer health equity related to an aspect of the cancer control continuum: prevention, screening and early detection, diagnosis, treatment, palliative care, or survivorship.
- **III. Preliminary Studies (if available; not required):** Provide results of your prior research that are relevant to this proposal; reprints or preprints may be included in the Appendix. Note that the entire application is considered confidential, including reports of unpublished research.
- IV. Research Design and Methods: Describe your proposed methods and procedures in enough detail to permit evaluation by other scientists. All cancer health equity applications must address two or more social determinants of health in relation to the following domains: economic; education; neighborhood and built environment; policy; social and community context; or factors impacting access to and provision of high-quality care. Discuss potential difficulties and limitations of the methods and procedures and provide alternative approaches.

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

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

10. LETTERS OF RECOMMENDATION (7.1)

In the Letter of Recommendation section, list the name, title and email addresses of three individuals, *other than* the *designated mentor(s)* on this application, who can critically appraise your qualifications. You will also provide this contact information on proposalCENTRAL so that they can access the site to upload their letters. There are specific instructions on the site for applicants and designated recommenders.

Ideally, letters will be provided by a graduate mentor, a member of a former dissertation committee, and a former research mentor. The letters should address character, motivation, maturity, general knowledge, ability to use research techniques, originality, specialized experience, and training.

You cannot submit your application until these letters have been provided on proposalCENTRAL.

For Resubmissions Only: Letters of recommendation can be reused if the application is resubmitted within a calendar year of the initial proposal. In order to resubmit your application, your recommenders must upload the letters on proposalCENTRAL again.

11. STATEMENT OF SCIENCE OUTREACH AND ADVOCACY (PAGE 8.1)

The ACS considers it important that scientists communicate the results of their research to a wide range of communities. Explain the potential impact of your proposed project on your community, and to the American Cancer Society's mission of eliminating cancer as a major health problem. Share any previous experiences in science outreach and advocacy. Describe your future plans for disseminating your work in the cancer arena through advocacy, awareness, education, or service. Please include your plans for sharing your research and research findings with your (non-academic) community members and for engaging with community partners in the dissemination process (not to exceed one page).

PART II - TRAINING AND MENTORING PLAN

The following sections must be prepared by the primary mentor (even if there are comentors).

12. PROPOSED TRAINING AND MENTORING (PAGE 9.1)

In three pages or less, describe the training and mentoring plan proposed for the applicant covering the full period of training requested, including all phases of training, research and didactic. Where appropriate, describe how this plan is tailored for the applicant.

This information will be used to evaluate the quality of the training experience and is an integral part of the overall assessment of the application. To aid in this evaluation, consider including the following information:

- The numbers of Postdoctoral Fellows and Graduate Students in the laboratory, and, if applicable, indicate approximately how many graduate students and fellows have completed their training in the mentor's laboratory during the past 3-5 years, and where they have landed in their careers.
- The importance of the proposed research to cancer.
- Whether the proposed research plan was prepared independently by the applicant or in collaboration with you.

Any comments about the postdoctoral applicant should be included here rather than in a separate letter. The Primary Mentor should explain the roles of the Co-Mentor(s) in the training plan. The Co-Mentors can provide a separate letter of support, which can be placed in the Appendix.

This plan is to be completed by the primary mentor. If there are co-mentors (or a mentoring team), only the primary mentor should complete PART II. All mentors must submit the Biographical Information requested in Section 14.

13. FACILITIES AVAILABLE (PAGE 10.1)

In 3 pages or less, describe the facilities available for the training program proposed.

14. BIOGRAPHICAL SKETCH OF MENTOR(S) (PAGE 11.1)

All mentors must complete the NIH Biosketch template, following the formats and instructions provided by the NIH. The Biographical Sketch may not exceed five pages

15. SUPPORT OF MENTOR (PAGE 12.1)

List all active and pending grant support including granting agency, title of project, direct costs (clearly indicate whether the amount reflects per year or total), and term.

16. COMPLIANCE STATEMENTS (PAGE 13.1)

Human Subjects

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

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

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

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

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

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

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

Collaborating sites. List any collaborating sites where research on human subjects will be performed and describe the role of those sites and collaborating investigators in performing the proposed research. Explain how data from the site(s) will be obtained, managed, and protected. *For additional protections for vulnerable populations, see http://www.hhs.gov/ohrp/policy/populations/index.html.

Vertebrate Animals

Provide your rationale for using live vertebrate animals including the:

- 7. Necessity for using the animals and species proposed;
- 8. Appropriateness of the strains, ages, genders of the animals to be used;
- 9. Justifications for, and appropriateness of, the numbers of animals proposed. When completing the Targeted Enrollment Table, select non-human subjects research and check the box that most appropriately describes your research.

Biohazards

Briefly describe whether any materials or procedures proposed are potentially hazardous to research personnel, equipment, and/or the environment. What protections will mitigate such risks? Include biological or chemical hazards.

Authentication of Key Biological and/or Chemical Resources

Briefly describe methods to ensure the identity and validity of key biological and/or chemical resources to be used in the proposed studies. These resources may or may not be generated with ACS funds and:

- may differ from laboratory to laboratory or over time;
- may have qualities and/or qualifications that could influence the research data; and
- must be integral to the proposed research.

These may include, but are not limited to, cell lines, specialty chemicals, antibodies, and other biologics. Researchers should transparently report how they have authenticated key resources, so consensus can emerge.

Standard laboratory reagents that are not expected to vary need not be included in the plan (e.g. buffers and other common biologicals or chemicals). After reviewers assess the information you provide in this Section, their questions will need to be addressed prior to an award. In this section, focus *only* on authentication and/or validation of key resources to be used in the study. Include all other information within the page limits of the research strategy. Applications that fail to comply may be dismissed.

Priority Focus on Health-Equity Research in the Cancer Control and Prevention Research Grants Program (750-word limit)

Applicants proposing health-equity research must upload a Cancer Prevention and Control Cancer Health Equity Statement Page **13.1**. In it, summarize the targeted area(s) of health equity, study population, and how the proposed research will contribute to improving health equity relevant to cancer.

How will your anticipated findings advance the field? This must pertain to an aspect of the cancer continuum and two or more of the social determinants of health (see Priority Area Focused on Health Equity description in the All Grants Policies, page 9)

Examples of research in this area include, but are not limited to, improvements in:

- risk reduction behaviors;
- access to cancer prevention;
- early detection, diagnosis, and/or treatment services;
- reducing cancer morbidity, mortality, symptom burden, or costs; and
- quality of care, quality of life, or health policy impact.

1. APPENDIX TO APPLICATION

In addition to the application templates, other key documents may be uploaded and submitted as part of the application. However, applicants are urged to include only highly relevant supporting documents. Appended materials may include:

- Letter from ACS Eligibility Committee confirming eligibility (if applicable)
- Recent reprints or preprints (optional)
- Clinical protocols (if applicable)

It is not necessary to number the pages of the Appendix, but list in order by categories (i.e., reprints, preprints, etc.) at the bottom of the Table of Contents.

APPENDIX A: REVIEWER GUIDELINE CRITERIA

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

PART I CANDIDATE

- A. STATEMENT OF EXPERIENCE AND CAREER GOALS OF APPLICANT
- B. BIOSKETCH OF APPLICANT
- C. LETTERS OF RECOMMENDATION [Provided online at proposalCENTRAL]
- D. TRAINING POTENTIAL

Relying on the contents of sections (A) thorough (D) above, critically evaluate the qualifications of the applicant considering the following items: goals and commitment to cancer research; past education; past training – board-eligible or board-certified, past research experience; number and impact of previous publications; and overall suitability of the candidate for this award. Provide an assessment of the confidential letters of recommendation, including research ability and potential, ability to plan and conduct research, knowledge of the field relevant to the proposed work, ability to work as a team, and personal characteristics. **To maintain confidentiality, please include this evaluation on the template so this content can be easily deleted prior to sharing with the applicant.**

Assess whether the fellowship broadens the training and experience of the applicant beyond what was obtained in their graduate work and aligns with the applicant's stated career goals.

REPLY TO PREVIOUS REVIEWS [IF APPLICABLE]

Note whether this is a resubmission and comment on the adequacy of the response to the prior critiques.

PART II PLANS FOR WORK UNDER FELLOWSHIP

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. In critiquing the research study, be specific and detailed about the following elements:

1. Significance: Does the project address an important problem or a critical barrier in the field? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or interventions that drive this field?

2. Approach: Are the hypothesis and aims appropriate for answering the research question(s)? Is the overall strategy, methodology, analyses and timeline well-reasoned and appropriate to accomplish the specific aims? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility? Will particularly risky aspects be managed?

4. Cancer Relevance: Is the proposed research important to cancer research? How is this research relevant to persons at risk for, or living with, cancer or their family members/caregivers? The relevance to cancer may be indirect, but the connection must be clearly articulated by the applicant.

5. Candidate/Research Team: Does the PI and research team (including mentors) have the training and experience needed to carry out the proposed research? Do team members have complementary skills and qualifications needed for successful implementation and analysis of the proposed research? 6. Environment: Will the scientific environment, in which the work will be done, contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

6. Statement of Science Outreach and Advocacy: (FEEDBACK OPTIONAL, THIS SECTION SHOULD NOT BE INCLUDED FOR CONSIDERATION OF SCORING). Does the outreach and advocacy plan present any concerns (including, but not limited to, research compliance, participant safety, and/or feasibility)? Do you have any suggestions to improve the plan?

PART III PROPOSED TRAINING AND MENTORING PLAN

A. PROGRAM GOALS AND PROPOSED TRAINING

Evaluate the appropriateness of the training activities (i.e., core curriculum studies, courses and lectures in enhancing the research training of the applicant, and their relevance to the applicant's career objectives).

B. INSTITUTIONAL RESOURCES AND ENVIRONMENT FOR TRAINING

Assess the suitability of the academic and research environment for the proposed training program. Consider 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. Assess whether the presence of these resources will directly benefit the candidate.

C. TRAINING EXPERIENCE OF MENTOR(S)

Evaluate the appropriateness of the mentor(s) experiences for their respective roles in the proposed training and mentoring plans. Consider the qualifications and reputation of the mentor(s) in cancer research and in training cancer researchers, the commitment of the mentor(s) to the plan, and the overall appropriateness of the mentor(s) and mentor(s) qualifications for the proposed research project.

D. BIOGRAPHICAL SKETCH OF MENTOR(S)

To assess qualifications of mentor and training/mentoring history. Will help aid in the assessment of parts (A) through (C) directly above.

E. SUPPORT OF MENTOR(S)

To convey the current funding of the mentor(s). This is critical because the budget for a PF award is predominantly stipend support.

F. MENTOR[S] COMMITMENT LETTER[S]

To aid in the assessment of parts (A) through (C) directly above.

PART IV COMPLIANCE STATEMENTS

1. Human Subjects. If the project involves research on humans, assess whether the plans for protection of human subjects from research risks is justified in terms of the scientific goals and research strategy proposed. For example, are the potential benefits and risks to subjects reasonable and appropriate given the study design? If applicable, are the plans to conduct sub-analysis by group, for data security and confidentiality, biohazards and data and safety monitoring adequate?

2. Inclusion of Women, Minorities, and Children. When the proposed project involves human subjects, evaluate the adequacy of the proposed plans for inclusion or exclusion of minorities, male and female genders, as well as children.

3. Vertebrate Animals. Evaluate the involvement of live, vertebrate animals as part of the scientific assessment according to the following points: 1) necessity for the use of the animals and species proposed; 2) appropriateness of the strains, ages, and gender of the animals; 3) justifications for, and appropriateness of, the numbers of animals proposed.

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

Priority Focus on Health Equity Research in the Cancer Control and Prevention Research Grants Program (ONLY for Cancer Control and Prevention applications)

For health equity applications in Cancer Control and Prevention, reviewers will assess the potential impact of the proposed study, if the specific aims are successfully accomplished. For example, how will this research: (1) substantially improve equity in access to cancer prevention, early detection, diagnosis, and/or treatment services; (2) accelerate efforts to reduce cancer burden or costs, improve quality of care, delivery of care or quality of life; or (3) impact public policy to advance health equity relevant to cancer? The reviewer critique should include a summary of the targeted area(s) of health equity proposed, the study population, determinates of health that will be explored and the levels of influence (individual, interpersonal, organizational, community, or public policy) being targeted.

RESEARCH PROFESSOR AND CLINICAL RESEARCH PROFESSOR

INSTRUCTIONS

PREPARING THE APPLICATION

PART I

<u>New applications</u> must provide all the information requested in Templates 1.1 through 8.1. <u>Renewal applications</u> should follow the Instructions found immediately after SECTION 10.

1. APPLICATION TEMPLATES

An application consists of several sections that must be uploaded before the application is submitted. Templates for these sections are available once an application is started on proposalCENTRAL.

The templates must be downloaded to a computer and completed offline. Detailed below are the instructions for completing the individual sections. *The sections must be converted into .pdf documents before being uploaded. Please see proposalCENTRAL's FAQ or call support at 1-800-875-2562 if you need assistance.*

2. TABLE OF CONTENTS (PAGE 1.1)

The Table of Contents is pre-numbered and should be limited to two pages. Complete by adding a list of items in the Appendix.

3. BIOGRAPHICAL INFORMATION OF APPLICANT (PAGE 2.1)

A. Personal Statement (maximum 2 pages)

Describe why you are well suited to be named an American Cancer Society Research Professor or a Clinical Research Professor. Relevant factors include aspects of your training, previous experimental work, technical expertise, and collaborators or scientific environment and service.

B. Mentoring and Leadership (maximum 2 pages)

Describe how you have enhanced your field in your role as a mentor and leader. As a part of your description, list the individuals you have trained, their current positions, and describe the impact you have had on their careers.

C. Contributions to Science (maximum 4 pages)

Describe up to five of your most significant contributions to your field. For each contribution, provide: the historical background that frames the scientific problem; the central finding(s); the influence of those finding(s) on progress within the field or their application to health or technology; and your specific role in the described work. Reference up to four peer-reviewed publications relevant to each contribution. The description of each contribution should be no longer than one half page including figures and citations.

In addition, please provide your complete and updated curriculum vitae, which includes leadership roles, mentorship, honors, awards and all publications in the Appendix.

4. RESEARCH SUPPORT (PAGE 3.1)

List all sources of research support, Federal, non-Federal or Institutional, available to you through research grants, cooperative agreements, contracts, fellowships, and other means. Describe all <u>active</u> support, and all applications <u>pending</u> review or award. Give the name of the granting agency, the grant number, the title of project, the amount and term, your role (e.g., principal investigator, co-investigator, collaborator) and your percent effort.

5. STRATEGIC PLANS DURING THE TERM OF THE AWARD (PAGE 4.1)

This section should not exceed 6 pages.

Describe your current strategic plans and future research and clinical (if applicable) activities.

The research and research-related clinical activities proposed **should not** simply be a continuation of your current work. Rather, the plans should describe a logical but novel strategic overview of your research plans and should reflect the exceptional nature of this Award.

Indicate the impact the Award would have on your program and outline how the Award will enable you to advance your research program in ways that would not be possible otherwise (i.e., what would you do if you had \$80,000 a year to spend to bring about significant change in your field?). While the peer reviewers will assess your past scientific contributions, they will also focus on your potential for continuing to be a leader in the field based, in part, on the strategic plans you propose in terms of its innovation, novelty, and feasibility.

In addition, reviewers will consider your qualifications as a mentor and as a spokesperson for the American Cancer Society in your area(s) of expertise. In the final analysis, they will evaluate past accomplishments and your potential to continue making significant contributions in research, mentorship and service that will lead to, or result in, a significant reduction in the cancer burden.

Please use the following format to describe your plans:

A. Strategic Direction

What knowledge gaps in your field remain to be filled? Concisely summarize and critically evaluate related work done by others and specifically state how you plan to strategically fill this void to advance scientific knowledge or aspects of clinical practice that are important for better understanding cancer or cancer patients. Articulate your vision for how you will advance your research discipline in the next five years, acknowledging top challenges in the field.

B. Innovation

- (1) Explain how the application challenges and seeks to shift current research or clinical practice paradigms.
- (2) Describe any novel theoretical concepts, approaches or methodologies, instrumentation or intervention(s) to be developed or used, and any advantage over existing methodologies, instrumentation, or intervention(s).
- C. Statement of Cancer Relevance (250 words This does not count toward the 6page limit)

This section of the application is important to the Stakeholders (non-scientific members) on the Peer Review Committees and to a number of general audiences including donors. The use of technical terminology or scientific jargon should therefore be avoided.

Describe the short- and long-term contributions the project is designed to make to control cancer. For basic studies relying on experimental models (rather than human cancer cells, tissues, or clinical data), explain how the successful completion of the proposed work will lead to a better understanding of the disease and/or improve our ability to prevent, detect, treat, or manage cancer or cancer patients.

For more clinically relevant projects involving the etiology, diagnosis, treatment and/or psychosocial or behavioral aspects of cancer in humans, outline the expected contribution of the study to controlling the overall cancer burden. This description might include: an estimate of the potential patient target population; anticipated effects on morbidity and/or mortality; possible impact on quality of life; and the extent to which the findings may be applicable beyond the specific aspect of cancer to be investigated.

6. REFERENCES (PAGE 5.1)

The list of references should correspond to the citations listed in the sections starting on Page 4.1. 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, the title of the article, the name of the book or journal, volume number, and inclusive page numbers. There is **no page limit** for the list of references.

7. LETTERS OF RECOMMENDATION (PAGE 6.1)

List the name, title and address of five individuals from whom you have requested letters of recommendation. These individuals must also be listed in the appropriate section of the electronic application. Listing them electronically will result in their being contacted immediately by email with a request to provide a reference and instructing them on how to submit the reference to proposalCENTRAL. You will see when the letters have been sent in, but they are submitted blindly, and **you will not be able to submit the application** until all the letters have been provided to the site.

PART II

The following sections must be prepared by the department head, dean, or equivalent official.

8. INSTITUTIONAL AND/OR DEPARTMENTAL COMMITMENT (PAGE 7.1)

Using the template provided, describe the institution's commitment to the research program of the candidate.

9. ENVIRONMENT (PAGE 8.1)

Briefly describe the environment available as it relates to the research program of the candidate.

10. APPENDIX

All supplementary materials (C.V., key reprints, preprints, etc.) included in the Appendix should be listed in the Table of Contents (Page 1.1 of the application).

RENEWAL APPLICATIONS ONLY

APPLICANTS ARE STRONGLY ADVISED TO CONTACT THE SCIENTIFIC DIRECTOR RESPONSIBLE FOR THE INITIAL PEER REVIEW.

Please note that only four templates are required for the Renewal application.

1. TABLE OF CONTENTS FOR RENEWAL AWARD (PAGE 1.1)

The Table of Contents is pre-numbered and should be limited to two pages. Complete by adding a list of items in the Appendix.

2. STRATEGIC PLANS DURING THE TERM OF THE RENEWAL AWARD (PAGE 2.1)

This section should not exceed 6 pages.

- **A.** Articulate your strategic vision of how you will continue to advance your research discipline for the next five years.
- **B.** Identify the top challenges in the field and the novel and innovative approaches you will use to address them.
- **C.** Describe how you will maximize productivity and overcome any real or perceived barriers that might impact the success of your program (e.g., change of institution, change in collaborators, grant support, other responsibilities, etc.).
- **D.** Indicate how you will continue to be a highly visible leader through mentoring, and service to both the American Cancer Society and your community.

3. REFERENCES (PAGE 3.1)

The list of references should correspond to the citations listed in the sections starting on Page 2.1. 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, the title of the article, the name of the book or journal, volume number, and inclusive page numbers. There is **no page limit** for the list of references.

4. PROGRESS REPORT FOR RENEWAL AWARD (PAGE 4.1)

Since the financial support provided by the Society is for the Professor's program and not for a specific research project, the renewal should focus on both the project as funded along with your entire research program. To this end, document your role as a high impact contributor and thought leader in your area of research since you were named an American Cancer Society Research or Clinical Research Professor by providing the following information:

A. Non-technical Progress Report (250-word limit)

The non-technical progress report is provided to American Cancer Society staff and may be given to donors or other Society supporters who do not have a scientific or oncology background. Therefore, please ensure the non-technical progress report is written in non-technical, lay language. Start your report with one or two sentences stating the relevance of the project to cancer or to specific cancer type(s). Then briefly describe your major research accomplishments to date with particular emphasis on discoveries you believe are novel or are seminal contributions to the understanding or treatment of cancer. Explain how the successful outcome of your project has impacted or could impact cancer patients, treatment, prevention, early detection and/or understanding of the disease.

NB: Information submitted as part of the non-technical progress report may be made available to the general public; therefore, do not include proprietary/confidential information.

B. Technical Progress Report (three-page limit)

Summarize the specific aims and your progress to date.

C. Outputs:

- 1. Oral presentations: Provide the conference name and indicate if the presentation was in a plenary session.
- 2. Publications: List only articles, book chapters, etc. Do not list abstracts. Indicate if in press or published. Provide the names of all authors, year of publication, title of the article, the name of book or journal, volume number, and inclusive page numbers.
- 3. Patents granted/applied for related to your research program.
- 4. New drugs, diagnostics, prognostics, devices, etc. developed as a result of your research program.
- 5. Adoption of new protocols/policies by community/agency/institutions as a result of your research program.
- 6. Other (specify)

D. Mentoring (three-page limit)

Describe how you have enhanced the field in your role as a mentor. Indicate the number of individuals you have trained and their current job titles. If trainees are in academic positions, include their institutions and academic rank. For all trainees, briefly describe how you have impacted each of their careers.

E. Community Service (3-page limit)

Provide examples of service to the national and international scientific and/or patient community.

F. Interaction with the National or Local American Cancer Society, or interaction with other community organizations in efforts to disseminate your research findings (3-page limit)

We are especially interested in what ACS activities you have you been involved in and when? Examples include:

- 1. Participation in ACS events/programs
- 2. Participation in other community events/programs
- 3. Participation by ACS staff/volunteers in events at your institution
- 4. Presentations to donors/other ACS volunteers

- 5. Tours of your facility for ACS staff, volunteers and/or donors
- 6. ACS-CAN membership and activities
- 7. Other interactions

G. Other Funding

Indicate whether you have received other grants/awards subsequent to the ACS award.

Provide:

- 1. Title of grant
- 2. Number of grants
- 3. Granting institution
- 4. Amount of award
- 5. Term of award

H. Recognitions and Awards

List any awards or special recognitions for your research or related activities.

In addition, please provide your complete and updated curriculum vitae, which includes leadership roles, mentorship, honors, awards and all publications/citations in the <u>Appendix.</u>

5. APPENDIX

All supplementary materials (C.V., key reprints, preprints, etc.) included in the Appendix should be listed in the Table of Contents (Page 1.1 of the application).

APPENDIX A: REVIEWER GUIDELINE CRITERIA

Evaluating New Research Professor and Clinical Research Professor applications: There are 4 components to be evaluated in a RP/CRP application:

- **1. Investigator:** Is the investigator regarded as a "thought-leader"? Does the investigator have a track record of high-impact publications? Is the investigator a leader in the cancer research community? Has the applicant made at least one seminal contribution to their field?
- 2. Research Program and Proposed Project: Is the applicant's cancer research program addressing a critical unmet need in innovative ways? Does this program have a likelihood of continued high impact discoveries for cancer research? Does the proposed project explore a new direction (technically and/or conceptually) rather than a continuation of current investigations? Are there other investigators doing similar work? In the case of Clinical Research Professor applications, a clinical component should be included.
- **3.** Mentoring: Does the investigator have a track record of mentoring trainees who have gone on to be successful in research? Is there evidence for a current commitment to mentoring?
- **4. Service:** Has the investigator demonstrated a commitment to serving the scientific community and beyond? While this could be demonstrated through service to the American Cancer Society, this is not required. A lack of prior participation in Society-sponsored activities should not be viewed as a weakness.
- PART IOBJECTIVE: Briefly describe the overarching goal(s) of the research
program and the general aims and potential impact of the proposed project.
- PART II INVESTIGATOR: Assess the impact, to date, that the applicant has had on cancer research. Evaluate the unique contributions of the investigator and whether he/she continues to be a leader in their area(s) of expertise. Is he/she likely to continue to be a leader into the future? Are their contributions more intellectual or technical in nature? Consider the content of the Letters of Recommendation when critically evaluating the applicant.
- PART IIIRESEARCH PROGRAM AND PROPOSED PROJECT: Evaluate the
significance, cancer relevance, and novelty of the overall research
program and specifically the proposed project. The research plan is not
intended to be as specific or detailed as a Research Scholar Grant but must
be scientifically sound, justified, and include a novel aspect of work for
the investigator. The award is intended to support the testing of innovative
ideas, not simply to supplement ongoing projects.

- PART IVMENTORSHIP: Evaluate the evidence that the applicant has
successfully mentored trainees, colleagues, etc. This may include, but is
not limited to, the number of graduate students/residents and postdoctoral
fellows that have gone on to successful positions in cancer research.
Mentoring may also be demonstrated through educational/training
activities.
- PART VSERVICE: Evaluate the applicant's commitment to service in the
scientific community and beyond. This could be demonstrated in many
ways including scientific leadership at an institutional, national or
international level, community outreach, and advocacy.

PHYSICIAN TRAINING AWARDS IN CANCER PREVENTION

PREPARING THE APPLICATION

Please read carefully the requirements set forth in the Policies, Physician Training Award in Cancer Prevention, before completing the application. Prospective applicants who have questions should contact the Society for clarification prior to submission of an application. Questions should be directed to:

Virginia Krawiec, MPA Scientific Director, Health Professional Training in Cancer Control

Stella Jones, Program Manager 404-329-5734 / <u>stella.jones@cancer.org</u>

COVER PAGES

The application cover pages include the Signature page with Assurances and Certifications, Contact page, and General Audience Summary. Most of the information collected online at proposalCENTRAL appears on the cover pages, such as applicant and institution information.

IMPORTANT: the *applicant's* mailing address must appear in the box with the headings "APPLICANT CURRENT INSTITUTION" and "MAILING ADDRESS." This is drawn from the information provided in the Professional Profile section of proposalCENTRAL.

Signatures. The department head and the applicant are required to sign the application. Please note that you need to complete the **General Audience Summary** at proposalCENTRAL. You **do not** need to complete a **structured technical abstract**.

1. APPLICATION TEMPLATES

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

2. TABLE OF CONTENTS (PAGE 1.1)

The Table of Contents is pre-numbered. Complete it by adding the Appendix information. *Note: there is no overall page limit for the completed application.*

3. REPLY TO PREVIOUS REVIEW (RESUBMISSIONS AND RENEWALS) (PAGE 2.1)

IF THE APPLICATION IS A NEW SUBMISSION, upload the provided template with "Not Applicable" in the body.

IF THE APPLICATION IS A RESUBMISSION, identify it as such on the cover page. Then clearly and briefly address the points raised in the previous reviews and direct the reader to the specific sections where text revisions have been made. Text changed in response to reviewers' comments should be identifiable in the revised application (e.g. bold type, line in the margin, underlining, etc.).

IF THE APPLICATION IS A RENEWAL, identify it as such on the cover page. Effective January 2017, the peer review committee will review the critiques of the most recent application as part of the evaluation of a new proposal. Include these critiques and document progress made toward addressing them by completing the Reply to Previous Review.

Insert copies of the previous critiques immediately after the Reply to Previous Review as illustrated in the Table of Contents.

4. PREVIOUS CRITIQUES (RESUBMISSIONS AND RENEWALS)

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

5. INSTITUTION INFORMATION (PAGE 3.1)

(Use the "Institution Information" template and continuation pages as necessary to answer the following questions.)

- Describe the applicant institution, e.g., is it a university, academic health center, department of public health, etc.?
- Address the institution's facilities, resources, equipment, and personnel (including the total number of professional staff).
- List any existing cancer epidemiology, control, and prevention activities at the institution or at the collaborating institutions.
- Indicate whether there is access to a cancer registry.

6. **RESIDENCY PROGRAM INFORMATION (PAGE 4.1):**

(Use the "Residency Program Information" template and continuation pages as necessary to provide the requested information for items 1-4.)

Provide all residency program information requested by questions 1-4, including current accreditation status. If the program was cited by ACGME during the most recent site visit, address any issues or concerns raised, and include a copy of the progress report. Answer Items 5-7 on continuation pages following your response to item 4.

5.

- a. Describe the overall structure of the program and its core components, including any existing training concentrations or tracks.
- b. Discuss the affiliation with a school of public health, including the cost of tuition for the master's degree.
- c. Describe existing and planned practicum training sites. Indicate whether there are memoranda of understanding with other agencies, including for research. **Note:** Letters of support from collaborating institutions that provide cancer prevention and control rotations must be included with the application (see "Required Letters").
- d. Describe changes to the residency program that are planned as a result of funding via this award. Outline the components to be added for the cancer prevention and control track that distinguish it from the existing program, e.g., core curriculum, other didactics, rotations, etc.
- 6. Provide **in chart form** the names and titles of key faculty for the proposed cancer prevention and control training program. Indicate in the budget the percent time, funded or in-kind, that each will devote to the proposed project. This information must be consistent with the description of roles and responsibilities requested in question #7 (following).
- 7. Describe the roles and responsibilities of the principal investigator and other key faculty (mentors and other experts in cancer prevention and control, cancer epidemiology, clinical cancer care) in the proposed training program and their qualifications for this function. Individuals named as key faculty with cancer control expertise must provide letters describing their roles, support, and commitment.

Resident Tables

- In the Table of PTACP Residency Program Graduates, include only residents supported with PTACP funds.
- In the Table of All Residency Program Graduates, list all other residents.
- For residents who completed training many years prior to this application, indicate in the last column the resident's last known position.
- Order both lists in chronological order, starting with the most recent.

Biographical Information for Principal Investigator and Key Faculty (PAGE 5.1 or 6.1) Include a biographical sketch for the principal investigator and for each of the listed key faculty [see Policies, 21. Requirements for Institutions]. Use the "Biographical Sketch" template and adhere to the format provided. The template may be used repeatedly as needed but must not exceed two pages. Provide the appropriate section number in the heading of the template (i.e., use 5.1 for first page of principal investigator form, and 6.1 for first page of key faculty forms).

Education/Training. Complete the educational block at the top of the page by providing the information requested. Postdoctoral training should include residency, internships and any fellowships. For fellowships, list title of position, mentor's name, and exact dates of training.

Complete sections A through E. Specific instructions for items A, B, and E are below.

- A. Certifications. List professional certifications and credentials with dates.
- **B.** Current Activities and Previous Positions (include academic and teaching responsibilities). List these in chronological order, concluding with your present position. State duration, title, and institution.
- **E. Publications.** Provide complete references for all peer-reviewed publications, including titles; 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, and book chapters).

7. PROGRAM GOALS AND DESCRIPTION (PAGE 7.1)

(Use the "Program Goals" template and continuation pages as necessary to answer the following questions.)

- 1. The institution must provide documentation of a supervised, well-defined program in preventive medicine with an emphasis on cancer prevention and control. List the overall goals and measurable objectives for the proposed program; describe the specific activities planned to support development of clinical, research, and teaching skills; and explain how the outcomes will be evaluated.
 - <u>Renewal applications</u> also should describe the history (i.e., number of grants thus far) and impact of the PTACP funding to date, by restating the objectives outlined in the previous application(s) and the progress to date in meeting them. Highlight measurable results, e.g., increase in graduates with cancer prevention and control focus, new collaborations, new rotations, new relationships that create sustainability. Provide an update about any deliverables that have resulted from the grant funding.

Include in the application Appendix copies of resident final reports from the last five years that were submitted to the American Cancer Society. Do not include attachments, such as publications. Copies of the residents' schedules also must be provided; the forms provided for ACGME site visits are acceptable. See the Appendix for an example format.

• <u>New applications</u> should describe the anticipated impact of these grant funds on the residency program. Ideally, identify measurable results of the cancer prevention and control program goals and objectives, such as increase in graduates with cancer prevention and control focus, new collaborations, new rotations, new relationships that

create sustainability. Describe any prior experience in providing cancer prevention and control training and how this factor will be leveraged.

This section should include information about how the residents will apportion their time over the two-year period of the award: teaching appointments, clinical responsibilities, participation in practicum site projects and programs, research opportunities, committee memberships, anticipated conference presentations/publication, etc.

Include a proposed two-year program schedule of activities for the PTACP resident(s).

Provide a table that shows the cancer prevention and control curriculum for the residents. Courses required of all PTACP residents as well as elective options should be included.

2. Proposed support of residents

Describe specific support to be provided to the residency training program by the institution, for example space, personnel, computers, other equipment, funds to attend conferences.

3. Resident recruitment

Provide explicit information about methods for recruiting residents to the proposed training program. Include details about the applicant pool and strategies, such as listing on the preventive medicine residency website, to reach prospective residents.

4. ACS Engagement Describe the plan for interaction between the residents and the American Cancer Society.

8. DETAILED BUDGET AND JUSTIFICATION OF BUDGET (PAGE 8.1)

Provide a budget, including both funded and in-kind activities, for the period of the award, detailing in the budget justification the proposed use of the funds provided by the ACS [see Policies].

Justify the need for personnel, supplies, travel, other items and all equipment costing over \$5000. It is expected that most (75% or more) of the funds will be used for direct support of the resident. Program development costs may be budgeted in the first year of funding. Explain in detail how the funds requested for other activities will be used. If the emphasis is not on resident support, the impact on cancer prevention and control training must be clearly justified.

As part of the justification, complete the provided table (p. 8.2) to indicate the overall residency program budget, broken down by source of income. Replace the table headings with the relevant income sources. If related grant funding is pending, include each potential funding source and describe its impact, if the grant is awarded, in the justification.

Budget Category Definitions

- Non-trainee expenses. List all key faculty (from Residency Program Information) and percent time.
- **Subcontracts**. If any portion of the proposed project 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.

- **Permanent Equipment**. Any item of nonexpendable property with a purchase cost per unit that equals or exceeds \$5,000 with a useful life of more than one year. List and justify each item separately.
- Supplies. Group into major categories (survey materials, computer software, etc.)
- **Travel**. Domestic travel only. Special consideration may be given to 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., pathology), computer time and scientific software, and equipment maintenance.

9. REQUIRED LETTERS

(Letters are submitted electronically.)

- Letters describing roles, support, and commitment from individuals named as key faculty with cancer control expertise.
- Letters of support from collaborating institutions that provide cancer prevention and control rotations.
- Letter of support from the local American Cancer Society.

The letters must be provided electronically on proposalCENTRAL. Provide the names and email addresses of the persons you ask to provide letters in the Required Letters section of the online application. This allows proposalCENTRAL to email those persons a link to the website and give them access to the site to upload their letters. There are specific instructions on the site for you and those who submit letters on your behalf. Your application cannot be submitted until these letters have been uploaded to -proposalCENTRAL.

10. APPLICATION APPENDIX

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

- The ACGME accreditation letter and residency progress report if relevant
- Copies of resident final reports and schedules

Appended materials may also include:

- Other letters of support
- Recent reprints or preprints

It is not necessary to number the pages of the Appendix, but please list items in the Table of Contents of the application.

APPENDIX A: SAMPLE OF GENERAL AUDIENCE SUMMARY

The ACGME accredited residency program in general preventive medicine and public health at the School of Medicine will provide physician training in cancer prevention and control through a well-defined and enriched curriculum track for resident awardees, featuring a variety of cancer prevention control research and practice experiences and related academic coursework.

The training is designed to develop board-certified preventive medicine specialists who will be future leaders in research, education, and interventions in cancer prevention and control, and will contribute to the accomplishment of national and ACS objectives for cancer control.

The Department of Preventive Medicine at the School of Medicine has several NIH-supported research projects in cancer prevention and control and operates related clinical services for hospital employees and other occupational populations.

The training program is building upon this rich resource in cancer control research and service, as well as on its longstanding affiliations with health departments, hospitals and other practicum training sites with experience and programs in cancer prevention and control.

APPENDIX B: CRITERIA FOR THE REVIEW OF APPLICATIONS

The following items are used by reviewers in evaluating applications for the Physician Training Award in Cancer Prevention.

Effective January 2017, renewal applications must include the critiques of the previous application and document progress made toward addressing them. Resubmitted applications should also include this section.

Reviewers should evaluate the adequacy of the response.

INSTITUTION INFORMATION

- Overall strength and reputation of institution and department of preventive medicine/occupational medicine.
- Commitment to cancer control of institution and department of preventive medicine/occupational medicine.

RESIDENCY PROGRAM

- Overall strength and reputation of the residency program and school of public health; proven ability to train personnel in preventive medicine/cancer control. *Special consideration: Is there a cancer prevention and control track distinguished from the general residency training? How so?*
- Affiliations with other institutions/agencies, e.g. public health department, cancer center. *Special consideration: Are there memoranda of understanding a) supportive of underserved populations or b) with entities engaged in cancer prevention and research?*
- Adequacy of institutional and departmental facilities and resources. *Special consideration: Does institutional support include tuition reduction?*

PRINCIPAL INVESTIGATOR AND KEY FACULTY

- Qualifications of principal investigator in preventive medicine and cancer control, including publication record.
- Qualifications of other faculty in preventive medicine and cancer control, including publication record.
- Appropriateness of all faculty, including principal investigator, to roles in training program; any special evidence of commitment to the training program, e.g., percentage of time available for participation.

PROGRAM GOALS AND DESCRIPTION

- Are program goals and objectives appropriate to the purpose of the grant program?
 - For a <u>renewal application</u>, consider the progress made toward achieving the goals stated in the original application. Are measurable results described, e.g., increase in graduates with cancer prevention and control focus, new collaborations, new

rotations, new relationships that create sustainability? Have any deliverables resulted from the grant funding to date?

- <u>New applications</u> should describe the anticipated impact of these grant funds on the residency program. For the program's goals and objectives, are anticipated measurable results identified such as an increase in graduates with cancer prevention and control focus, new collaborations, new rotations, new relationships that create sustainability? Is there prior experience in providing cancer prevention and control training, and how well will this factor be leveraged?
- Are proposed academic, clinical, research, teaching or other activities appropriate to accomplish program goals and objectives in cancer prevention and control, including the expected applicant pool and methods/strategies for recruiting residents?
- Assess the curriculum in cancer prevention and control. Are required as well as elective courses described?
- What is the commitment of space, funding, support personnel, computers, supplies, other equipment, funds to attend conferences, etc., in support of the residency program? *Special consideration: Is there any external support (e.g., state health department, local foundation)?*
- Overall adequacy of facilities and resources, including faculty and staff.
- Is there a well-defined plan of interaction between the residents and the American Cancer Society?

BUDGET AND JUSTIFICATION OF BUDGET

- Are all key faculty listed with a percent time commitment to the PTACP project?
- Are the budget and justification appropriate, including the proportion of total budget allocated for direct support of residents?
- Assess the overall program budget. Are there any outside sources of support for the residency program? Are there any specifically for the proposed training in cancer prevention and control?

APPENDIX C: EXAMPLE RESIDENT SCHEDULE

PREVENTIVE MEDICINE RESIDENT SCHEDULE

Resident:

Level: Year:

ACADEMIC ACTIVITIES	Sept.	Oct.	Nov.	Dec.	Jan.	Feb.	Mar.	Apr.	May	June	July	Aug.
Principles of Epidemiology (3 credits)												
Principles of Public Health (3 credits)												
Introductory Biostatistics (3 credits)												
Preventive Medicine Seminars (2 hrs. per week)												
Journal Club (8 hrs. per month)					\leftarrow							
Applied Epidemiology (3 credits)									+			
Community Health Education (3 credits)												
Emergency Preparedness (3 credits)						-						
Data Management (3 credits)						-						
PRACTICUM ACTIVITIES:												
City DPH (3-6 hrs/week)	↓											
Community Assessment, and school (3-10 hrs/ week)		•										
State DPH (8-16 hrs/week)										•		
Medical Ethics/State Medical Society (5 hrs/ month)												

Medical Journalism ABC News (40-50 hrs/wk)						${\longleftarrow}$		
Commonwealth Medicine VNA Preparedness (3 hrs/wk)					-			
HIV/AIDS South Africa (40-50 hrs/wk)							•	
TEACHING ACTIVITIES:								
Prevention Counseling Exercise, Med School (4/hrs/month)								
RESEARCH:								
Development and presentation of research proposal (5-10 hrs/week)								
CLINICAL ACTIVITIES:								
Correctional Health (8 hrs/wk)	•							

APPENDIX A: SAMPLES OF GENERAL AUDIENCE SUMMARIES

The examples below are for all grants except for the Intuitional Research Grant (see page 36) and Physician Training Award in Cancer Prevention (see page 99) for samples.

1. Clinical and Epidemiology Research

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

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

2. Cancer Control and Prevention Research:

Title: Distrust as a Barrier to Cancer Screening and Prevention

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

We will focus on a population composed of African American, Caucasian, and Hispanic women to elucidate the relationship between health care related distrust and historically disadvantaged ethnic/racial minorities. These women will be between the ages of 40 and 70, a group for whom effective cancer screening is available and recommended. In order to determine the patterns of

health care related distrust and association between distrust and attitudes towards cancer screening and prevention, we will conduct a population-based telephone survey in the United States. We will examine several types of cancer related health behaviors and investigate how distrust may act as a barrier to adopting these behaviors. These behaviors will include adherence with current cancer screening recommendations for breast, cervical and colon cancer as well as willingness to use new interventions for cancer screening and prevention.

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

3. Basic Research:

Title: Regulation of Chromosome Segregation in Human Cells

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

APPENDIX B: 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 nucleosome organization of different ARS loci in relation to those regions where the parental DNA double-strand unwinds first. We will correlate the sites of initiation with sites of unwinding and place those into context with the overall chromatin structure at a given chromosomal ARS locus.

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

APPENDIX C: CLASSIFICATION CATEGORIES - AREAS OF RESEARCH

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

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

Applicants are asked to select from the following codes:

1 – BIOLOGY

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

1.1 Normal Functioning

Examples of science that would fit:

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

1.2 Cancer Initiation: Alterations in Chromosomes

Examples of science that would fit:

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

1.3 Cancer Initiation: Oncogenes and Tumor Suppressor Genes

- 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, TGFbeta, GM-CSF, etc.

• Research into the biology of stem cell tumour initiation

1.4 Cancer Progression and Metastasis

Examples of science that would fit:

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

1.5 Resources and Infrastructure

Examples of science that would fit:

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

2 – ETIOLOGY

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

2.1 Exogenous Factors in the Origin and Cause of Cancer

- Research into the role of lifestyle factors such as smoking, chewing tobacco, alcohol consumption, parity, diet, sunbathing, and exercise in the origin and cause of cancer or increasing the risk of cancer
- Research into the social determinants of cancer such as crime, housing dilapidation (poor housing), neighbourhood level socioeconomic status and services and their relationship to cancer incidence and mortality etc.
- Studies on the effect(s) of nutrients or nutritional status on cancer incidence
- Development, characterization, validation, and use of dietary/nutritional assessment instruments in epidemiological studies and to evaluate cancer risk
- Environmental and occupational exposures such as radiation, second-hand smoke, radon, asbestos, organic vapors, pesticides, and other chemical or physical agents
- Infectious agents associated with cancer etiology, including viruses (Human Papilloma Virus-HPV, etc.) and bacteria (helicobacter pylori, etc.)
- Viral oncogenes and viral regulatory genes associated with cancer causation
- Contextual Factors Contributing to Cancer Incidence (e.g., race/ethnicity, socioeconomic status, neighborhood factors, community factors, built environment).

2.2 Endogenous Factors in the Origin and Cause of Cancer

Examples of science that would fit:

- Free radicals such as superoxide and hydroxide radicals
- Identification /confirmation of genes suspected of being mechanistically involved in familial cancer syndromes; for example, BRCA1, Ataxia Telangiectasia, and APC
- Identification/confirmation of genes suspected or known to be involved in ""sporadic"" cancer events; for example, polymorphisms and/or mutations that may affect carcinogen metabolism (e.g., CYP, NAT, glutathione transferase, etc.)
- Investigating a role for stem cells in the etiology of tumours

2.3 Interactions of Genes and/or Genetic Polymorphisms with Exogenous and/or Endogenous Factors Examples of science that would fit:

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

2.4 Resources and Infrastructure Related to Etiology

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

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

3 – PREVENTION

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

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

Examples of science that would fit:

- Research on determinants of personal behaviors, such as physical activity, sun exposure, and tobacco use, known to affect cancer risk and interventions (including educational and behavioral interventions directed at individuals as well as population-based interventions including social marketing campaigns, environmental supports, and regulatory, policy and legislative changes) to change determinants or to target health inequalities.
- Directed education to specified populations of patients, health care providers, and at-risk groups about cancer risk and prevention and relevant interventions with the intent of promoting increased awareness and behavioral change. This includes communication of lifestyle models that reduce cancer risk, such as communicating smoking and tobacco cessation interventions, genetic counselling, or targeting/addressing health inequalities.

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

- Quantification of nutrients, micronutrients, and purified nutritional compounds in cancer prevention studies
- Development, characterization, validation, and use of dietary/nutritional assessment instruments to evaluate cancer prevention interventions
- Research on determinants of dietary behavior and interventions to change diet (including educational and behavioral interventions directed at individuals as well as population-based interventions including social marketing campaigns, environmental supports, and regulatory and legislative changes) to change diet

- Education of patients, health care providers, at-risk populations, and the general population about cancer risk and diet
- Communicating cancer risk of diet to underserved populations, at-risk populations, and the general public
- Communication of nutritional interventions that reduce cancer risk
- Nutritional manipulation of the microbiome for cancer prevention

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
- Other (non-vaccine) preventive measures such as prophylactic surgery (e.g., mastectomy, oophorectomy, prostatectomy etc.), use of antibiotics, immune modulators/stimulators or other biological agents.
- Manipulation of the microbiome for cancer prevention (e.g. fecal transplant)

3.4 Vaccines

Examples of science that would fit:

• Vaccines for prevention, their discovery, mechanism of action, development, testing in model systems, and clinical testing (e.g., HPV vaccines)

3.5 Complementary and Alternative Prevention Approaches

Examples of science that would fit:

- Discovery, development, and testing of complementary/alternative medicine (CAM) approaches or other primary prevention interventions that are not widely used in conventional medicine or are being applied in different ways as compared to conventional medical uses
- Mind and body medicine (e.g., meditation, acupuncture, hypnotherapy), manipulative and bodybased practices (e.g., spinal manipulation, massage therapy), and other practices (e.g., light therapy, traditional healing) used as a preventive measure.

3.6 Resources and Infrastructure Related to Prevention

- Informatics and informatics networks; for example, patient databanks
- Specimen resources (serum, tissue, etc.)
- Epidemiological resources pertaining to prevention
- Clinical trials infrastructure
- Statistical methodology or biostatistical methods
- Centers, consortia, and/or networks
- Development and characterization of new model systems for prevention, distribution of models to scientific community or research into novel ways of applying model systems, including but not limited to computer-simulation systems, software development, in vitro/cell culture models, organ/tissue models or animal model systems. Guidance note: this should only be used where the focus of the award is creating a model. If it is only a tool or a methodology, code to the research instead.

• Education and training of investigators at all levels (including clinicians and other health professionals), such as participation in training workshops, conferences, advanced research technique courses, and Master's course attendance. This does not include longer term research based training, such as Ph.D. or post-doctoral fellowships.

4 – EARLY DETECTION, DIAGNOSIS, AND PROGNOSIS

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

4.1 Technology Development and/or Marker Discovery

Examples of science that would fit:

- Discovery or identification and characterization of markers (e.g., proteins, genes, epigenetic), and/or technologies (such as fluorescence, nanotechnology, etc.) that are potential candidates for use in cancer detection, staging, diagnosis, and/or prognosis
- Use of proteomics, genomics, expression assays, or other technologies in the discovery or identification of markers
- Defining molecular signatures of cancer cells, including cancer stem cells (e.g., for the purposes of diagnosis/prognosis and to enable treatment decision planning in personalized/stratified/precision medicine)

4.2 Technology and/or Marker Evaluation With Respect to Fundamental Parameters of Method

Examples of science that would fit:

- Development, refinement, and preliminary evaluation (e.g., animal trials, preclinical, and Phase I human trials) of identified markers or technologies such as genetic/protein biomarkers (prospective or retrospective) or imaging methods (optical probes, PET, MRI, etc.)
- Preliminary evaluation with respect to laboratory sensitivity, laboratory specificity, reproducibility, and accuracy
- Research into mechanisms assessing tumor response to therapy at a molecular or cellular level

4.3 Technology and/or Marker Testing in a Clinical Setting

- Evaluation of clinical sensitivity, clinical specificity, and predictive value (Phase II or III clinical trials), including theranostics and prediction of late/adverse events
- Quality assurance and quality control
- Inter- and intra-laboratory reproducibility
- Testing of the method with respect to effects on morbidity and/or mortality
- Study of screening methods, including compliance, acceptability to potential screenees, and
 receiver-operator characteristics. Includes education, communication (e.g., genetic counselling
 and advice on screening behavior based on cancer risk factors), behavioral and
 complementary/alternative approaches to improve compliance, acceptability or to reduce
 anxiety/discomfort, and evaluation of new methods to improve screening in healthcare settings.

• Research into improvements in techniques to assess clinical response to therapy

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

Examples of science that would fit:

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

5 – TREATMENT

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

5.1 Localized Therapies - Discovery and Development

- Discovery and development of treatments administered locally that target the organ and/or neighboring tissue directly, including but not limited to surgical interventions, cryotherapy, local/regional hyperthermia, high-intensity, focused ultrasound, radiotherapy, and brachytherapy
- Therapies with a component administered systemically but that act locally (e.g., photodynamic therapy, radioimmunotherapy, radiosensitizers and theranostics)
- Development of methods of localized drug delivery of systemic therapies e.g., Pressurized Intraperitoneal Aerosol Chemotherapy (PIPAC), direct intratumoral polymers/gels/nanoparticles/microsomes etc.
- Research into the development of localized therapies to prevent recurrence

• Guidance note: localized therapies are considered to be localized when the site of action is the same as the site of administration.

5.2 Localized Therapies - Clinical Applications

Examples of science that would fit:

- Clinical testing and application of treatments administered locally that target the organ and/or neighboring tissue directly, including but not limited to surgical interventions, cryotherapy, local/regional hyperthermia, radiotherapy, and brachytherapy.
- Clinical testing and application of therapies with a component administered systemically but that act locally (e.g., photodynamic therapy, radiosensitizers and theranostics, Pressurized Intraperitoneal Aerosol Chemotherapy (PIPAC), direct intratumoral polymers/gels/nanoparticles/microsomes etc.)
- Phase I, II, or III clinical trials of promising therapies that are administered locally
- Side effects, toxicity, and pharmacodynamics
- Clinical testing of localized therapies to prevent recurrence and prevent and treat metastases

5.3 Systemic Therapies - Discovery and Development

Examples of science that would fit:

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

5.4 Systemic Therapies - Clinical Applications

Examples of science that would fit:

 Clinical testing and application of treatments administered systemically such as cytotoxic or hormonal agents, novel systemic therapies such as immunologically directed therapies (treatment vaccines, antibodies, antibiotics, theranostics or other biologics), gene therapy, angiogenesis inhibitors, apoptosis inhibitors, whole body hyperthermia, bone marrow/stem cell transplantation, and differentiating agents, adjuvant and neo-adjuvant treatments, systematically-delivered nanoparticles/microsomes, cell-based therapies, manipulation of the microbiome etc.

- Phase I, II, or III clinical trials of promising therapies administered systemically
- Side effects, toxicity, and pharmacodynamics
- Clinical testing of systemic therapies to prevent recurrence and prevent and treat metastases

5.5 Combinations of Localized and Systemic Therapies

Examples of science that would fit:

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

5.6 Complementary and Alternative Treatment Approaches

Examples of science that would fit:

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

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

- Informatics and informatics networks; for example, clinical trials networks and databanks
- Mathematical and computer simulations
- Specimen resources (serum, tissue, etc.)
- Clinical trial groups
- Clinical treatment trials infrastructure
- Epidemiological resources pertaining to treatment
- Statistical methodology or biostatistical methods
- Drugs and reagents for distribution and drug screening infrastructures
- Centers, consortia, and/or networks
- Development and characterization of new model systems for treatment, distribution of models to scientific community or research into novel ways of applying model systems, including but not limited to computer-simulation systems, software development, in vitro/cell culture models, organ/tissue models or animal model systems. Note: this should only be used where the focus of the award is creating a model. If it is only a tool or a methodology, code to the research instead.
- Reviews/meta-analyses of clinical effectiveness of therapeutics/treatments
- Education and training of investigators at all levels (including clinicians and other health professionals), such as participation in training workshops, conferences, advanced research

technique courses, and Master's course attendance. This does not include longer term research based training, such as Ph.D. or post-doctoral fellowships.

6 - CANCER CONTROL, SURVIVORSHIP, AND OUTCOMES RESEARCH

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

6.1 Patient Care and Survivorship Issues

Examples of science that would fit:

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

6.2 Surveillance

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

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

6.3 Population-based Behavioral Factors

Examples of science that would fit:

- Research into populations' attitudes and belief systems (including cultural beliefs) and their influence on behaviors related to cancer control, outcomes and treatment. For example, how populations' beliefs can affect compliance/interaction with all aspects of the health care/service provision
- Research into the psychological effects of genetic counselling
- Research into behavioral barriers to improving cancer care/survivorship clinical trial enrollment

6.4 Health Services, Economic and Health Policy Analyses

Examples of science that would fit:

- Development and testing of health service delivery methods
- Interventions to increase the quality of health care delivery
- Impact of organizational, social, and cultural factors on access to care and quality of care, including studies on variations or inequalities in access among racial, ethnic, geographical or socio-economic groups
- Studies of providers such as geographical or care-setting variations in outcomes
- Effect of reimbursement and/or insurance on cancer control, outcomes, and survivorship support
- Health services research, including health policy and practice and development of guidelines/best practice for healthcare delivery across the diagnostic/preventive/treatment spectrum
- Analysis of health service provision, including the interaction of primary and secondary care
- Analyses of the cost effectiveness of methods used in cancer prevention, detection, diagnosis, prognosis, treatment, and survivor care/support
- Ethical, legal or social implications of research/health service delivery (e.g. genetic counselling)
- Research into systemic or operational barriers to trial enrollment

6.5 Education and Communication Research

- Development of generic health provider-patient communication tools and methods (e.g., telemedicine/health)
- Tailoring educational approaches or communication to different populations (e.g., social, racial, geographical, or linguistic groups)
- Research into new educational and communication methods and approaches, including special approaches and considerations for underserved and at-risk populations

- Research on new methods and strategies to disseminate cancer information/innovation to healthcare providers (e.g., web-based information, telemedicine, smartphone apps, etc.) and the effectiveness of these approaches
- Research on new communication processes and/or media and information technologies within the health care system and the effectiveness of these approaches
- Media studies focused on the nature and ways in which information on cancer and cancer research findings are communicated to the general public
- Education, information, and assessment systems for the general public, primary care professionals, or policy makers
- Research into barriers to successful health communication

6.6 End-of-Life Care

Examples of science that would fit:

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

6.7 Research on Ethics and Confidentiality

Examples of science that would fit:

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

6.8 – Historical code [no longer used]

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

- Informatics and informatics networks
- Clinical trial groups related to cancer control, survivorship, and outcomes research
- Epidemiological resources pertaining to cancer control, survivorship, and outcomes research
- Statistical methodology or biostatistical methods pertaining to cancer control, survivorship and outcomes research
- Surveillance infrastructures
- Centers, consortia, and/or networks pertaining to cancer control, survivorship and outcomes research

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