

AMERICAN CANCER SOCIETY ALL GRANT APPLICATION INSTRUCTIONS EFFECTIVE JULY 2023

ELECTRONIC APPLICATION DEADLINE: April 1 and October 15

AMERICAN CANCER SOCIETY, INC. Extramural Discovery Science Department

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

MISSION

The American Cancer Society's mission is to improve the lives of people with cancer and their families through advocacy, research, and patient support, to ensure everyone has an opportunity to prevent, detect, treat, and survive cancer.

AMERICAN CANCER SOCIETY

ALL GRANT APPLICATION INSTRUCTIONS

CONTENTS

GEN	IERAL INFORMATION	3
1.	AMERICAN CANCER SOCIETY (ACS) GRANT APPLICATION SYSTEM	3
2.	FORMAT	3
3.	UPDATES OF INFORMATION	3
4.	REQUIRED INFORMATION	4
5.	GENERAL AUDIENCE SUMMARY	6
6.	STRUCTURED TECHNICAL ABSTRACT	6
7.	STATEMENT OF CANCER RELEVANCE AND IMPACT	7
8.	JUSTIFICATION OF PROJECT ALIGNMENT TO RESEARCH PRIORITIES	7
9.	SELECTION OF RESEARCH PRIORITIES	7
10.	PROJECT CODING	7
11.	ASSURANCES AND CERTIFICATION	7
12.	PI DATA	8
13.	RESUBMISSION	8
14.	APPLICATION SUBMISSION AND REQUIRED E-SIGNATURE	9
15.	SPECIFIC INSTRUCTIONS BY GRANT MECHANISMS	10
RES	EARCH SCHOLAR GRANT	10
INST	FITUTIONAL RESEARCH GRANT	25
DISC	COVERY BOOST GRANT	34
MISS	SION BOOST GRANT	47
CLIN	IICIAN SCIENTIST DEVELOPMENT GRANT	57
POS	TDOCTORAL FELLOWSHIP	73
RES	EARCH PROFESSOR AND CLINICAL RESEARCH PROFESSOR	83
APP	ENDIX A: EXAMPLES OF GENERAL AUDIENCE SUMMARIES	90
APP	ENDIX B: EXAMPLE OF STRUCTURED TECHNICAL ABSTRACT	92
APP	ENDIX C: EXAMPLES OF PROJECT ALIGNMENT TO RESEARCH PRIORITIES	93
APP	ENDIX D: CLASSIFICATION CATEGORIES - AREAS OF RESEARCH	95

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" > Scroll to see our Grant Mechanisms and Funding Opportunities
- Select link to your grant, which opens the electronic application process at ProposalCentral.
- Follow instructions for login/register, completion, and submission.
- Key steps:
 - Filter on the "Grant Opportunities" Tab > "Choose American Cancer Society" > "Review Grant Types" > "Select Grant" > Apply Now"
 - Enter Project Title (unless already displayed) > SAVE. This permits access to other application components.
 - Saved applications are stored under "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:** <u>></u> 0.5 inches all around unless a form with different margins is supplied in the Application Templates.
- Page numbering: Number the pages in upper right corner according to the proposal sections listed in the Table of Contents.
- **Do not number:** Signature Page, Contact Page, General Audience Summary, Structured Technical Abstract, Statement of Cancer Relevancy and Impact, Justification of Alignment with Research Priorities, Budget & Justification, if applicable, or the 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 Discovery Science 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 150 characters including spaces; avoid abbreviations if possible. **Note:** The title will be truncated after 81 characters on the title page.

Principal Investigator/Applicant Information: Some (or all) of the required information from your Professional Profile may already be displayed. 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 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).

A **Mentor** assists in the scientific and professional development of the mentee. A Primary Mentor should be identified and listed as Key Personnel ONLY for Postdoctoral Fellowships and Clinician Scientist Development Grants. If additional mentors are identified, they should also be listed as Key Personnel.

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

REQUIRED SUPPORTING DOCUMENTS FOR NAMED PERSONNEL

Personnel	Designated "Key"	Biosketch	"Other Support" Documentation	Included in Budget & Justification	Letters
Principal Investigator	Yesa	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	

	No	No	No	No	Letter of Agreement/Support ^b
Consultant	Yes	Yes	Yes, if paid ^b	Yes, if paid ^c	Letter of
Consultant	No	No	No	Yes, if paid	Agreement/Support ^b
Other	No	No	No	Yes	No
Mentor(s)d	Yes	Yes	Yes	Yes ^d	Letter of Agreement/Support

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

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

Degree and Independent Position Dates: Under Professional Profile, indicate the date (months and year) your terminal degree was awarded and when your first independent faculty position (or equivalent) began, if applicable.

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 under Professional Profile, even if that number is zero.

MSI Designation: Indicate using the radio buttons whether the PI's institution is a US Department of Education designated Minority Serving Institution (MSI). If yes, then select the type of MSI from the dropdown list. Some common MSI combinations are provided in the dropdown menu, but the list is not exhaustive. Use the text box to enter the type if your institution's MSI or combination is not in the list.

MSIs and Abbreviations:

- ANNH: Alaska Native and Native Hawaiian
- AANAPISI: Asian American and Native American Pacific Island Serving Institution
- HSI: Hispanic Serving Institution
- HBCU: Historically Black Colleges and Universities
- NASNTI: Native American Indian Serving Non-Tribal Institution
- PBI: Predominantly Black Institution
- TCU: Tribal Colleges and Universities

Institutional Official: Indicate the name and address of the official authorized to sign for the institution. Institutional Officials may electronically sign the application if required by the institution, but this is not required by ACS for submission. The PI must give the Institutional Official access to the application for e-signing to be completed. Provide a mailing address for disbursement of funds, in the event that your grant is awarded funding.

Technology Transfer Officer (TTO): Indicate the name and email address of the TTO. The TTO is responsible for technology transfer and other aspects of the commercialization of research that takes place at a university. The TTO will be responsible for reporting all IP updates to the ACS should the project be awarded funding.

^b For postdoctoral fellows, technicians, and graduate students, supporting documents are not required.

^c If Key Personnel are not being paid, enter \$0 for the amount requested; percent effort is required. Note that the percent effort indicated on the budget tool in ProposalCentral can be different than the requested compensation.

^d For mentored grants (CSDG, PF), include the Primary Mentor and other mentors, if applicable, as Key Personnel. Only CSDGs should include the mentor(s) in the budget/budget justification.

Department Chair: Indicate the name, department, and email address of the Department Chair. The electronic signature of the Department Chair is not required by the ACS.

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

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

ORCID Identifier: ORCID provides a persistent digital number that you own and control, and that identifies you from every other researcher. Please provide an ORCID identifier if you have one. To add the ORCID ID, click Professional Profile and connect/register for an ID. Once connected, return to your proposal, and click Save.

Program Office and Committee Code: Indicate the scientific program and peer review committee you think best aligns with the proposed science. Applicants will be notified of the assigned committee before peer review begins. The program offices make final committee assignment decisions based on the best fit for the application.

5. GENERAL AUDIENCE SUMMARY

The general audience summary provides an overview of the proposed research for people who are **not** trained in the sciences. This summary may be read by peer review stakeholders, ACS staff members, potential donors, and the public. **Stakeholders** are individuals without formal scientific or medical training who are full voting members of peer review panels. The stakeholder uses the general summary to evaluate how the proposed work will benefit cancer patients and their families.

- **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. <u>Therefore</u>, do not include proprietary/confidential information.

The general audience summary should **not** duplicate the structured technical abstract and 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 Appendix A.

This form is limited to 3,100 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. If this abstract is required there will be a space for it on ProposalCentral. The structured technical abstract is a summary of the proposed research or scholarly project for general scientific audiences. See examples of Structured Technical Abstracts in Appendix B.

Organize the abstract into the following sections:

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

This form is limited to 3,100 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. STATEMENT OF CANCER RELEVANCE AND IMPACT

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.** This form is limited to 1,500 characters including spaces and will truncate at that point.

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?

8. JUSTIFICATION OF PROJECT ALIGNMENT TO RESEARCH PRIORITIES

Explain how your proposed project aligns to the selected research priority/priorities. If your project aligns to multiple priority areas, provide additional justification of the alignment to those areas in this section as well. Please make sure that the priority area or areas are noted in the statement. Note: This form is limited to 1,500 characters, including spaces. If the character limit is exceeded in this section, which is evaluated, it will be truncated. Examples of research priority alignment statements are provided in Appendix C.

9. SELECTION OF RESEARCH PRIORITIES

Select the research priority or priorities to which your proposed project most strongly aligns and indicate the percent alignment. If multiple priorities are selected, the total should equal 100%. You are required to select a research priority area. Descriptions of the research priorities can be found in the All Grant Applications Policies document (pages 4-6).

10. 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 Appendix D for specific terms and examples.

11. 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.

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

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

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

Submission of Approval Documentation: 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. The Institution Official who signs during the grant activation process is responsible for confirming that approval has been granted for the research to begin. In addition, certification of the approval, clearly labeled with the assigned ACS application number, must be uploaded to ProposalCentral within 3 months of grant activation. Failure to comply may result in withholding of payments and/or cancellation of funding.

Note: Applications for the Institutional Research Grant (IRG) 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.

12. PI DATA

The PI demographic information is for use by the Extramural Discovery Science department. While "prefer not to disclose" is an option, we **strongly encourage** all applicants to specify their gender, race, ethnicity, and sexual orientation. We use this information for statistical purposes to understand the diversity of our applicant pool. We are committed to investing in a diverse research workforce and this data enhances our ability to develop inclusive policies and new funding opportunities to address current limitations. *This information is not accessible to peer reviewers and is not considered at peer review.* By sharing this information with us, you help the American Cancer Society track our progress and identify areas that need improvement.

13. RESUBMISSION

All resubmissions must create a new application on ProposalCentral. Please see grant-specific policies for the allowable number of resubmissions.

Resubmission guidelines:

- Submit a complete application electronically via ProposalCentral
- The title of the project can be altered but the application <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.
- Provide the peer review committee code from the previous application on the title page.

14. APPLICATION SUBMISSION AND REQUIRED E-SIGNATURE

We are now only accepting electronic submissions with e-signatures.

- All application attachments, including the Appendix, must be uploaded as .pdf documents.
- Validate the application on ProposalCentral. An application that has not been validated cannot be electronically submitted.
- Applications must be electronically submitted on ProposalCentral by 11:59 PM ET on the specified deadline date. If the deadline falls on a weekend or holiday, applications will be accepted the following business day.
- The applicant's electronic signature is required on the Signature Page. The e-signature of the Institution Signing Official and the Department Head are optional but available for use should the institution require them. In order to e-sign an application, the signees must be included in the application Contacts in ProposalCentral.
- Technical questions regarding the electronic application process should be directed to Altum at https://proposalcentral.com/ or 1-800-875-2562.

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

15. SPECIFIC INSTRUCTIONS BY GRANT MECHANISMS

RESEARCH SCHOLAR GRANT INSTRUCTIONS

1. COVER PAGES

Complete all fields, which include mandatory e-signature for the principal investigator. We provide text boxes for e-signatures for the departmental chair (or equivalent) and institutional officials to accommodate institution-specific requirements for proposal submissions, but neither is required for submission to ACS. Note: the PI must enable other users' access to the application on ProposalCentral to permit their e-signatures. 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 2 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 5 pages.

5. REPLY TO PREVIOUS REVIEW (PAGE 3.1)

IF THE 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, figures, or tables where edits have been made. Revisions should be easily identifiable in the revised application (e.g., bold type, italicized, or underline type). This section should not exceed 3 pages.

6. PREVIOUS CRITIQUES (resubmissions only)

For applications submitted before Spring 2021, 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. If you are resubmitting a grant that was reviewed Spring 2021 or later, go to the "Submitted" page, select "View Review Info," click "Print" to save it as a .pdf. Upload the document to your new application with the other proposal sections.

7A. 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 (I).

The same proposal may be submitted to other 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** (not to exceed 1 page). List the objectives and goals of your proposed research and briefly describe the scientific aims.
- **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 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 timeline can be helpful.
- **F.** Experimental Details (optional not to exceed 3 pages). This section is available if more indepth descriptions of the experimental design, technologies, or assays are needed to convey the specific approaches and procedures proposed.
- **G. Environment.** Briefly describe the space and equipment available to carry out the proposed research (e.g., space designated specifically for your research program, shared space and/or core facilities). Investigators must have an institutional commitment of research facilities, and the amount of committed space must be verified (see Statement of Institutional Support in Section 13 below). This section is required and especially important for all non-tenure track applicants.
- H. Statement of Science Outreach and Advocacy (not to exceed 1 page). 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 to save lives, celebrate lives, and lead the fight for a world without cancer. 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.
- **I. References.** Each literature citation should include title, authors, book or journal, volume number, page numbers, and year of publication. There is no page limitation; this section is not included in the 12-page limit of Sections (B) through (E).

7B. 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, Treatment AND Survivorship Services

Research to be funded by this RFA should focus on the changes in national, state, and/or local policy and the response to these changes by healthcare systems, insurers, payers, communities, practices, and patients.

Only resubmitted applications will be accepted for the RSGI grant mechanism. Applicants planning to submit a new proposal in this research area should apply for the standard RSG, if they meet eligibility requirements.

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 (I).

- **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 timeline can be helpful.

F. Potential for Knowledge Transfer and Experimental Details (3 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 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 <u>Cancer Action Network</u> (ACS CAN).

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. Briefly describe the space and equipment available to carry out the proposed research (e.g., space designated specifically for your research program, shared space and/or core facilities). Investigators must have an institutional commitment of research facilities, and the amount of committed space must be verified (see Statement of Institutional Support in Section 13 below). This section is required and especially important for all non-tenure track applicants.
- H. Statement of Science Outreach and Advocacy (not to exceed 1 page). 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 to save lives, celebrate lives, and lead the fight for a world without cancer. 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.
- **I. References.** Each literature citation should include title, authors, book or journal, volume number, page numbers, and year of publication. There is no page limitation; this section is not included in the 12-page limit of Sections (B) through (E).

7C. RESEARCH PLAN AND ENVIRONMENT – Priority Area Focused on Cancer Health Equity (PAGE 4.1)

Key Words and Definitions

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.

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

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 (I).

A. Specific Aims (not to exceed 1 page). List the objectives and goal(s) of the research proposed and briefly describe the Specific Aims within 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 that 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.

- Explain how the application challenges and seeks to shift current social, political, research, or clinical practice paradigms in relation to health equity.
- 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.
- Explain any refinements, improvements, or new applications of theoretical concepts, models, methodologies, technologies, or interventions.
- 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 will 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, 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 timeline can be helpful.
- **F.** Potential for Knowledge Transfer and Experimental Details (3 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. Briefly describe the space and equipment available to carry out the proposed research (e.g., space designated specifically for your research program, shared space and/or core facilities). Investigators must have an institutional commitment of research facilities, and the amount of committed space must be verified (see Statement of Institutional Support in Section 13 below). This section is required and especially important for all non-tenure track applicants.
- H. Statement of Science Outreach and Advocacy (not to exceed 1 page). 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 to save lives, celebrate lives, and lead the fight for a world without cancer. 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.

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

8. DETAILED BUDGET

Complete the budget page located online at ProposalCentral. For applications submitted in April, use a start date of January 1 of the next year. For applications submitted in October, use a start date of July 1 of the next year.

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 entered. List all key personnel (defined as individuals who will participate actively in the design and/or execution of the studies) other than the PI. 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. If a Key Person is not receiving salary, you can request \$0 for salary, but their percent effort is still required. Their effort and contribution to the project should be outlined in the Budget Justification even if they are not being compensated.

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:

- See above for definitions of 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 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: Equipment that equals or exceeds \$5,000 with a useful life of more than one year is not 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
 costs 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 are not allowable expenditures.
- **C. Supplies.** Group supplies into major categories (e.g., glassware, chemicals, radioisotopes, survey materials, animals, etc.).
- **D. Travel.** Any foreign travel requires **pre-approval** by your Scientific Office. Domestic travel expenses do not require pre-approval.
- **E. Miscellaneous Expenditures.** List specific amounts for each item. Examples of allowed expenditures include publication costs and special fees (e.g., 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 direct costs on the online budget detail page on ProposalCentral. Each subcontract should be listed separately. 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.

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. If there is a subcontract(s), 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. If a subcontract is receiving indirect costs, list the indirect costs for each institution separately in the indirect costs section of the budget form.

Example: Budget Indirect Costs Year 1 for Standard RSG

Primary Institution Indirect	20% primary institution direct cost total
Subcontract 1 Indirect	20% subcontract 1 direct cost total
Subcontract 2 Indirect	20% subcontract 2 direct cost total
Total Indirect Costs	\$40,000 IDC

Note: Applicants should not budget above or below the allowable indirect cost rate.

H. Total Amount Requested. Budget totals should reflect a maximum duration of 4 years.

The maximum allowable budget is \$960,000: \$200,000 direct costs per year and 20% indirect costs (\$40,000) for the 4-year project period.

Starting Fall 2023, all new RSG applications across all research programs must be 4-year projects. Resubmission of applications that were previously submitted for RSGI or RSG-HE applications under different guidelines will be allowed.

The amount on the application title page should match the total costs in the detailed budget section.

Note: For budgets that do not request the maximum allowable amount, if the grant is funded, the ACS will round the total to the nearest thousand dollars. We encourage applicants to request a budget amount that is rounded to an even thousand dollars.

9. JUSTIFICATION OF BUDGET

Provide budget justification on the template. 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 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.

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 ACS 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 ACS Scientific Director makes 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 PI. 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 ACS.

Provide the following information separately for the PI 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 ACS). Provide for each award:
 - a. Source of funds
 - 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. Role (e.g., PI, co-PI, co-I, etc.) and 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 ACS).
 - a. Source of funds
 - 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. Role (e.g., PI, co-PI, co-I, etc.) and 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 one award if both are approved for funding. The ACS does not negotiate partial funding of grants with overlapping specific aims.

Please notify the Scientific Director if a pending extramural grant is funded during the peer review process since this could affect the feasibility of the Pl's proposed effort (for cases of no scientific overlap) and possibly eligibility (for cases of scientific overlap).

- **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. 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. The institution is required to ensure IRB approval is obtained for the grant to

start, and the approval documentation is uploaded into ProposalCentral within 3 months of grant activation.

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 biospecimens, 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.

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

IACUC approval must be obtained before animal work begins. An IACUC approval letter must be uploaded to ProposalCentral immediately upon approval.

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 and chemical hazards, if applicable.

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 do not need to 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.

Cancer Health Equity Research Statement (750-words)

Applicants proposing health-equity research must upload a Cancer 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)

Provide the following information for the Principal Investigator only:

- 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.
- Details of the institutional commitment to support the applicant's salary and research program.
- The current term of the applicant's appointment.

These details should be confirmed by the Department Chair in the Statement of Institutional Support.

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 written by the Department Chair.

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)

REVIEWER GUIDELINE CRITERIA

For Health Equity applications submitted to the Clinical and Cancer Control Research Program there are additional criteria that need to be considered. Please ignore these criteria if the application you are reviewing is not a Health Equity Application.

Priority Focus on Health Equity Research in the Clinical and Cancer Control Research Program

Reviewers will assess the potential impact of the proposed research in advancing cancer health equity if the specific aims are successfully accomplished. Applicants are instructed to compose their research question, background and significance, cancer relevance, innovation, approach and cancer health equity statement using the following terms and concepts.

For each section, focus on the strengths and weaknesses. Your final score should align with your written critique.

1. ALIGNMENT WITH ACS RESEARCH PRIORITY AREAS

Has the applicant identified and appropriately justified how their project fits within one or more ACS research priority areas?

2. CANDIDATE

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).

3. REPLY TO PREVIOUS REVIEWS [IF APPLICABLE]

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

4. RESEARCH PLAN

Provide a brief overview of the project. In the following sections focus on the strengths and weaknesses, rather than summarizing.

5. RESEARCH PLAN - SIGNIFICANCE AND CANCER RELEVANCE

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? 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.

For Health Equity Applications also consider: Does the project address an important problem or a critical barrier to progress in the field of cancer health equity? Has the investigator clearly indicated two or more social determinants of health they assess to be root causes of health disparities or inequities in some aspect of the cancer control continuum? How will the findings impactfully change concepts, methods, technologies, treatments, services, or interventions that drive this field? Your overall impact rating should reflect how this research will either: (1) substantially improve equity in access to cancer prevention, early detection, diagnosis, palliative care, treatment services or survivorship; (2) accelerate efforts to reduce cancer burden or costs, improve quality of care, delivery of care or quality of life; or (3) impact of public policy to advance health equity relevant to cancer? How is this research relevant to persons at risk for, or living with, cancer and their family members and/or caregivers and friends? Will this research inform strategies to address structural societal barriers (economic, political, or social) that influence health or the ability to access or receive high-quality care?

6. RESEARCH PLAN - 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?

For Health Equity Applications also consider: How does this research challenge or seek to shift current understanding of social, economic, political, research, or clinical practice paradigms in relation to health equity. Will any novel theoretical concepts, models, methodologies, technologies, or interventions be developed or utilized to provide meaningful improvements or address critical needs or gaps?

7. RESEARCH PLAN - INVESTIGATOR/RESEARCH TEAM

Does the PI and research team have the training and experience needed to carry out the proposed research?

For Health Equity Applications also consider: Does the PI and research team (including mentors if applicable) 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 conduct the research? Is there adequate health equity expertise on the research team or mentoring team?

8. RESEARCH PLAN - 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?

For Health Equity Applications also consider: Are the hypothesis and specific aim(s) appropriate for answering the cancer health equity research question? Is the research framed in the context of the ACS cancer health equity definition and in the context of at least two social determinants of health? Is the overall strategy, methodology, data collection, analyses, and timeline well-reasoned and appropriate to accomplish the specific aims of the project? 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, and will particularly risky aspects be managed? For large multilevel studies, does the research plan incorporate two or more social determinants of health and two or more levels of influence (individual, interpersonal, organizational, community, or public policy)? Is it clear how the funding will contribute to achieving health equity?

9. RESEARCH PLAN - ENVIRONMENT AND RESOURCES

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?

10. 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?

11. BUDGET

NOT TO BE CONSIDERED IN SCORING

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? 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. Describe any suggested budget changes using 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.

13. COMPLIANCE STATEMENTS

NOT TO BE CONSIDERED IN SCORING

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 the plans for conducting sub-analysis by group, data security and
confidentiality, biohazards and data and safety monitoring adequate?

- 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.
- **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.
- 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.

14. HEALTH EQUITY APPLICATIONS ONLY: CANCER HEALTH EQUITY STATEMENT

The reviewer critique should include a summary of the targeted area(s) of health equity proposed, the study population, social determinates of health that will be explored, the level(s) of influence (individual, interpersonal, organizational, community, or public policy) being targeted and the anticipated contribution(s) their findings will have in achieving cancer health equity. Assess the degree to which this statement aligns with the ACS cancer health equity definition and how well the contents of this statement are integrated in the research plan.

INSTITUTIONAL RESEARCH GRANT INSTRUCTIONS

1. COVER PAGES

Complete all fields, which include mandatory e-signature for the principal investigator. We provide space for e-signatures for the departmental chair (or equivalent) and institutional officials to accommodate institution-specific requirements for proposal submissions, but neither are required for submission to ACS. Note: the PI must enable other users' access to the application on ProposalCentral to permit their e-signatures. 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

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. 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.

3. 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.

4. 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 3 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. 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. If your application was submitted before Spring 21, 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. If you are resubmitting a grant that was reviewed in Spring 21 or later, go to the "Submitted" page, select "View Review Info," click "Print" to save it as a .pdf. Upload the document to your application with the other proposal sections.

5. DESCRIPTION OF THE PROGRAM (PAGE 3.1)

This section must be limited to 4 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:

- o the relationship between the institutions;
- o the status of cancer research at the other site(s);
- o the expected growth in the IRG applicant pool;
- o the inclusion of faculty from the other institution on the IRG review committee [along with biographical sketches (see Section 7)]; and
- o 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 cancerrelated 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?).

6. CAREER DEVELOPMENT ACTIVITED 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;
- quidance on developing collaborative research relationships, and
- advice on balancing an academic career and one's personal life.

7. 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 faculty rank, 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 Research	Clinical Research	Cancer Control and Population Sciences	Total
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*.

8. BIOGRAPHICAL INFORMATION FOR THE PRINCIPAL INVESTIGATOR (PAGES 6.1 & 7.1)

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.**

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

A demonstrated interaction among the local ACS, the ACS Cancer Action Network (ACS CAN), 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 ACS 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.

10. 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.

11. 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.

12. 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 application.

Effective with 2022 IRG applications, three pilot project grants per year is the maximum that may be requested. The amount for each pilot project grant is \$40,000 in direct costs for a one-year project period.

If matching funds are to be provided by the institution, please explain their nature and amount. Institutions may supplement the pilot project awards.

Applicant Pool: The amount of funds requested is to support applicants eligible for pilot project grants. Describe here the number of beginning investigators new to or engaged in cancer research who are not principal investigators of an NIH R01 or equivalent grant (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.

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.

13. DOCUMENTATION OF APPLICANT POOL SIZE (PAGE 12.1) - New Applications Only

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 an NIH R01 or equivalent grant (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.

14. EXAMPLES OF RESEARCH TO BE SUPPORTED (PAGE 13.1) - New Applications Only

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:

15. SUMMARY TABLES (PAGES 12.1 – 17.1) – Renewal Applications Only

Using the templates for Tables I through VI, please provide the requested information for the past **seven** award years, or for the number of years in effect for grants of less duration. <u>Tables 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 for each 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 each grantee

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 **seven** 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 **seven-year** period. Provide subtotals for each year and an overall total in the space indicated.

16. AWARDEE PROJECTS

Current Pilot Project Grant Applications (up to 5 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 (2 to 3 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.

17. 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:

- Biographical Sketches of the IRG review committee
- Examples of how the local IRG Review Committee publicizes the availability of funds;
- Evidence of interaction with the local American Cancer Society; and
- Memorandum of Understanding (MOU) documenting a consortium arrangement with another institution.

Appended materials may also include:

Letter of support from the ACS 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.

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 nurturing 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 \$40,000 award to \$55,000 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.

CRITERIA FOR THE REVIEW OF APPLICATIONS

The following items are used by reviewers in evaluating applications for IRGs.

1. REPLY TO PREVIOUS REVIEW

State whether the application is a resubmission or renewal. Renewal applications must include the critiques of the previous application, and document progress made toward addressing the points made by the reviewers. For resubmitted applications, detail the candidate's responsiveness to previous critiques, focusing on the strengths and weaknesses of their reply.

2. DESCRIPTION OF PROGRAM

Provide an overview of the academic environment, and the potential applicant pool size. Describe unique aspects of the institution or any strategic efforts underway to expand cancer-related activities, especially research, which could impact faculty recruitment. How will faculty be recruited? Describe the institution(s) applying for an IRG. Detail the expertise of their research programs, and availability of early career investigators who can apply for funding.

How will the IRG 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, an explanation should be provided.

3. CAREER DEVELOPMENT ACTIVITIES FOR BEGINNING INVESTIGATORS

Describe the mentoring and career development activities proposed. What formal mechanisms will be used to foster early career investigators? How will the success of these activities be evaluated? Are the proposed activities relevant and appropriate for cancer research career development?

4. LOCAL COMMITTEE COMPOSITION

What is the composition of the review panel? What are the panel members' areas of expertise? What is the term for appointees? What are the qualifications of the committee chair PI? Is there broad representation across all schools and departments from which applications are expected? Will ACS representatives be participating in the committee?

5. INTERACTION WITH LOCAL ACS

How will IRG recipients engage with their local ACS? What activities are planned, and how are these activities advertised, supported, and prioritized? Is there evidence of interaction between the institution, including IRG pilot project grantees, and the local ACS Region office or with ACS CAN. In some areas of the country, this is the only ACS grant there is, and special consideration should be given for these interactions.

6. PROCEDURE FOR PUBLICIZING AVAILABILITY OF FUNDS

How will IRG funding be advertised? What methods of communication will be used? How frequently will funding availability be advertised? Do all departments and schools know about the grant? Are the numbers of applicants commensurate with the pool size?

7. 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? Is there feedback to the applicants?

8. 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, how does the number of applications align 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.

9. 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?

10. EXAMPLES OF RESEARCH TO BE SUPPORTED (new applications only)

Are the examples of pilot projects relevant to cancer, and is the potential research high quality?

11. APPLICATIONS AND AWARDS – TABLES I, II, V (renewal applications only)

How many applications are received, approved, and funded? What is the funding rate? What is the range of priority scores? 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?

12. PUBLICATIONS AND GRANTS – TABLES III, IV, VI, INDIVIDUAL PROGRESS REPORTS (renewal applications only)

Consider the overall productivity of the researcher supported by IRG funds, including all publications and grants not just those resulting from IRG pilot projects. Tracking of publications and awards should go back for seven years (excluding the current year) or the length of the award, if less. How many articles were published that are relevant to IRG funding? How many extramural awards have been obtained by IRG grantees? The cancer relevance of the research supported by individual allocations is also a factor in the evaluation of renewal requests for continued support.

DISCOVERY BOOST GRANT INSTRUCTIONS

PREPARING THE APPLICATION

1. COVER PAGES

Complete all fields, which include mandatory e-signature for the principal investigator. We provide text boxes for e-signatures for the departmental chair (or equivalent) and institutional officials to accommodate institution-specific requirements for proposal submissions, but neither is required for submission to ACS. Note: the PI must enable other users' access to the application on ProposalCentral to permit their e-signatures. 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.

Requests for Applications (RFAs): If you are responding to an RFA, select the appropriate RFA from the list on the cover page or select "N/A" if you are submitting a standard DBG application. You are not required to submit the DBG application to an RFA.

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 <u>upload as .pdf documents</u> <u>before submitting the online application</u>. 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 2 pages.

4. BIOGRAPHICAL SKETCH OF APPLICANT (PAGE 2.1)

Complete the NIH Biosketch template. Follow the formats and instructions provided by the NIH. **NOTE: The Biographical Sketch may not exceed 5 pages.**

5. REPLY TO PREVIOUS REVIEWS (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. Note: Only one resubmission is allowed for Discovery Boost Grant applications.

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, underline type, etc.). **This section should not exceed 3 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 click "Print" to save it as a .pdf. Upload the document to your new application with the other proposal sections.

7A. RESEARCH PLAN AND ENVIRONMENT (PAGE 4.1)

Section A below (Specific Aims) should not exceed 1 page. Sections B-E below must not exceed 5 pages. These page limits do not apply to Sections (F) through (I).

The same proposal may be submitted to other 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** (not to exceed 1 page). List the hypotheses, objectives, and goals of your proposed research and briefly describe the scientific aims. In addition, state how the pilot award will enable establishment of a new significant research direction.
- **B. Background and Significance.** Summarize and critically evaluate relevant work done by your research team and others. Specifically state how the successful completion of the work proposed will advance scientific knowledge and/or the application of that knowledge for reducing burdens from cancer.

C. Innovation

- Explain how the application challenges and seeks to shift current cancer research.
- Describe novel theoretical concepts, approaches, or methodologies to be developed or used, and the advantage they offer over existing ones.
- Explain refinements, improvements, or new applications of theoretical concepts, models, approaches, methodologies, technologies, or interventions.
- **D. Preliminary Studies.** While preliminary data are not expected or required for this pilot grant mechanism, there should be sufficient evidence to support 'boosting' a novel discovery or new significant research direction in cancer. You may therefore choose to 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 timeline can be helpful.
- **F. Experimental Details** (optional not to exceed 3 pages). This section is available if more indepth description of the experimental design, technologies, or assays are needed to convey the specific approaches and procedures proposed. This section is also appropriate for articulating specifics regarding how you plan to use findings from this research to inform a larger study.
- **G. Environment.** Briefly describe the space, resources, and equipment available to carry out the proposed research (e.g., space designated specifically for your research program, shared space and/or core facilities), and include details of how this environment will support your research. Investigators must have an institutional commitment of research facilities, and the amount of committed space must be verified (see Statement of Institutional Support in Section 13 below).

- H. Statement of Science Outreach and Advocacy (not to exceed 1 page). 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 to save lives, celebrate lives, and lead the fight for a world without cancer. 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.
- **I. References.** Each literature citation should include title, authors, book or journal, volume number, page numbers, and year of publication. There is no page limitation; this section is not included in the 5-page limit of Sections (B) through (E).

7B. RESEARCH PLAN AND ENVIRONMENT – Priority Area Focused on Cancer Health Equity (PAGE 4.1)

Key Words and Definitions

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.

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

Section (A) below (Specific Aims) should not exceed 1 page. Sections (B) through (E) below must not exceed 5 pages. This page limit does not include Sections (F) through (I).

- **A. Specific Aims** (not to exceed 1 page). List the objectives and goal(s) of the research proposed and briefly describe the Specific Aims within 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 that 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

- Explain how the application challenges and seeks to shift current social, political, research, or clinical practice paradigms in relation to health equity.
- 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.
- Explain any refinements, improvements, or new applications of theoretical concepts, models, methodologies, technologies, or interventions.

- 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.
- **F.** Potential for Knowledge Transfer and Experimental Details (3 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.** Briefly describe the space and equipment available to carry out the proposed research (e.g., space designated specifically for your research program, shared space and/or core facilities). Investigators must have an institutional commitment of research facilities, and the amount of committed space must be verified (see Statement of Institutional Support in Section 13 below). This section is required and especially important for all non-tenure track applicants.
- H. Statement of Science Outreach and Advocacy (not to exceed 1 page). 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 to save lives, celebrate lives, and lead the fight for a world without cancer. 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.
- **I. References.** Each literature citation should include title, authors, book or journal, volume number, page numbers, and year of publication. There is no page limitation; this section is not included in the 5-page limit of sections (B) through (E).

8. DETAILED BUDGET

Complete the budget page located online at ProposalCentral. For applications submitted in April, use a start date of January 1 of the next year. For applications submitted in October, use a start date of July 1 of the next year.

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

NOTE:

- See above for definitions of 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 that equals or exceeds \$5,000 with a useful life of more than one year. List
 separately and justify the need for each item of permanent equipment. Note: the cost of
 permanent equipment is not included in the direct cost total used to calculate indirect
 costs.
- Small or expendable equipment. Defined as expendable property with a purchase cost
 per unit that is less than \$5,000 and/or that has a short service life (<1 year). Note: the
 cost of small or expendable equipment may be included in the direct cost total used to
 calculate indirect costs.
- General purpose equipment. Equipment such as computers 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 are not allowable expenditures.
- **C. Supplies.** Group supplies into major categories (general office supplies, survey materials, participant materials, etc.)
- **D. Travel.** Any foreign travel requires **pre-approval** by your Scientific Office. Domestic travel expenses do not require pre-approval.
- **E. Miscellaneous Expenditures.** List specific amounts for each item. Examples of allowed expenditures include publication costs and special fees (e.g., 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 direct costs as a line item in the online budget detail page on ProposalCentral. Each subcontract should be listed separately. Provide a categorical breakdown of costs using the Subcontractor Budget and Justification form, using one form per subcontractor. Upload the form(s) when complete, entering subcontractor name in the "describe attachment" field.

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 costs allowance of up to 20% of the direct costs, excluding permanent equipment. If there is a subcontract(s), 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. If a subcontract is receiving indirect costs, list the indirect costs for each institution separately in the indirect costs section of the budget form.

Example: Budget Indirect Costs Year 1

Primary Institution Indirect	20% primary institution direct cost total
Subcontract 1 Indirect	20% subcontract 1 direct cost total
Subcontract 2 Indirect	20% subcontract 2 direct cost total
Total Indirect Costs	\$25,000 IDC

Note: Applicants should not budget above or below the allowable indirect cost rate.

H. Total Amount Requested. Budget totals should reflect a maximum duration of 2 years and a maximum of \$125,000 direct costs plus up to \$25,000 indirect costs per year for a total maximum award amount of \$300,000. The amount on the application Title Page should match the total costs in the detailed budget section.

Note: For budgets that do not request the maximum allowable amount, if the grant is funded, the ACS will round the total to the nearest thousand dollars. We encourage applicants to request a budget amount that is rounded to an even thousand dollars.

9. JUSTIFICATION OF BUDGET

Provide budget justification on the template provided. Justify all items of permanent equipment costing over \$5,000 as well as 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 expended funds are essential to the successful conduct of the project, and why there are no alternatives.

Provide details of contractual arrangements with key personnel in this section.

10. BIOGRAPHICAL INFORMATION OF KEY PERSONNEL (PAGE 5.1)

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

11. OTHER SUPPORT (PAGE 6.1)

The ACS 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*. Scientific Directors 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; and
- Awards that provide only salary support for the Principal Investigator. In the latter case, if the salary support for the Pl's contribution to the project is covered by the other agency, no additional salary support for the Pl 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
 - 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. Role (e.g., PI, co-PI, co-I, etc.) and 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).
 - a. Source of funds
 - 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. Role (e.g., PI, co-PI, co-I, etc.) and 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 one award if both are approved for funding.

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

- **C. Institutional Support.** Provide the following information for the Principal Investigator only:
 - a. Details of the institutional commitment to support the applicant's salary and research program.
 - b. A description of the space committed to the project.
 - 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.

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 each person will play with sufficient detail for evaluation of the value of the individual contribution.

13. COMPLIANCE STATEMENTS (PAGE 8.1)

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. The institution is required to ensure IRB approval is obtained for the grant to start, and the approval documentation is uploaded into ProposalCentral within 3 months of grant activation.

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 biospecimens, 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.

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

IACUC approval must be obtained before animal work begins. An IACUC approval letter must be uploaded to ProposalCentral immediately upon approval.

Provide your rationale for using live vertebrate animals including the:

- Necessity for using the animals and species proposed.
- Appropriateness of the strains, ages, genders of the animals to be used.

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 and chemical hazards, if applicable.

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.

Cancer Health Equity Research Statement (750-words)

Applicants proposing health-equity research must upload a Cancer 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)

The applicant's Department Chair (or equivalent) should provide the following information for the Principal Investigator only:

• A description of any start-up funds provided by the institution to the applicant if the applicant is within 10 years of starting their first independent faculty position. An award of start-up funds

does not decrease the likelihood of ACS support and can be important evidence of institutional commitment.

- Details of the institutional commitment to support the applicant's salary and research program, including salary support and dedicated space.
- Details of how the environment and resources at the institution will directly support and contribute to the success of the candidate's research.
- The current term of the applicant's appointment.
- The Department's long-term goals for the applicant's career

Non-tenure track applicants should also include a more detailed description of the space committed to the project. 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.

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 the 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 (if applicable)

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

REVIEWER GUIDELINE CRITERIA

For Health Equity applications submitted to the Clinical and Cancer Control Research Program there are additional criteria that need to be considered. Please ignore these criteria if the application you are reviewing is not a Health Equity Application.

Priority Focus on Health Equity Research in the Clinical and Cancer Control Research Program

Reviewers will assess the potential impact of the proposed research in advancing cancer health equity if the specific aims are successfully accomplished. Applicants are instructed to compose their research question, background and significance, cancer relevance, innovation, approach and cancer health equity statement using the following terms and concepts.

For each section, focus on the strengths and weaknesses. Your final score should align with your written critique.

1. ALIGNMENT WITH ACS RESEARCH PRIORITY AREAS

Has the applicant identified and appropriately justified how their project fits within one or more ACS research priority areas?

2. CANDIDATE

Provide an overall evaluation of the candidate's academic, clinical, and/or scientific qualifications. Does the candidate have the experience and resources to carry out the proposed project? Is there confidence that the candidate can secure subsequent funding once this pilot project has concluded?

3. REPLY TO PREVIOUS REVIEWS [IF APPLICABLE]

If applicable, detail the candidate's responsiveness to previous critiques, focusing on the strengths and weaknesses of their reply.

4. RESEARCH PLAN

Provide a brief overview of the project.

5. SIGNIFICANCE AND CANCER RELEVANCE

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 and/or technical capability improve? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field? How is this research relevant or how may it ultimately impact persons at risk for, or living with, cancer and their family members and/or caregivers? The relevance to cancer may be indirect and/or long-term, but the connection must be clearly articulated by the applicant.

For Health Equity Applications also consider: Does the project address an important problem or a critical barrier to progress in the field of cancer health equity? Has the investigator clearly indicated two or more social determinants of health they assess to be root causes of health disparities or inequities in some aspect of the cancer control continuum? How will the findings impactfully change concepts, methods, technologies, treatments, services, or interventions that drive this field? Your overall impact rating should reflect how this research will either: (1) substantially improve equity in access to cancer prevention, early detection, diagnosis, palliative care, treatment services or survivorship; (2) accelerate efforts to reduce cancer burden or costs, improve quality of care, delivery of care or quality of life; or (3) impact of public policy to advance health equity relevant to cancer? How is this research relevant to persons at risk for, or living with, cancer and their family members and/or caregivers and friends? Will this research inform strategies to address structural societal barriers (economic, political, or social) that influence health or the ability to access or receive high-quality care?

6. INNOVATION/IMPROVEMENT

What is the potential that the proposed study will challenge and seek to shift current research understanding or clinical practice by utilizing novel theoretical concepts, approaches, methodologies, instrumentation, or interventions? Does the research propose meaningful improvements or address critical gaps? Will the project open new and highly innovative areas for investigation? These high risk/high reward projects should be highly innovative.

For Health Equity Applications also consider: How does this research challenge or seek to shift current understanding of social, economic, political, research, or clinical practice paradigms in relation to health equity. Will any novel theoretical concepts, models, methodologies, technologies, or interventions be developed or utilized to provide meaningful improvements or address critical needs or gaps?

7. INVESTIGATOR/RESEARCH TEAM

Does the PI and research team have the training and experience needed to carry out the proposed research?

For Health Equity Applications also consider: Is the health equity expertise on the research team adequate?

8. APPROACH

DBGs are intended to support exploratory projects and pilot test high risk/high reward ideas or establish feasibility. Will the proposed project generate preliminary data that has the potential to secure additional grant funding? Is the overall strategy, methodology, data collection, analyses, and timeline well-reasoned and appropriate to accomplish the specific aims of the project? Where appropriate, are proposed recruitment and/or case ascertainment methods well developed? Is the sample size adequate? Are potential pitfalls, alternative approaches, benchmarks for success, and future plans articulated?

For Health Equity Applications also consider: Are the hypothesis and specific aim(s) appropriate for answering the cancer health equity research question? Is the research framed in the context of the ACS cancer health equity definition and in the context of at least two social determinants of health? Is it clear how the findings will contribute to achieving health equity?

9. ENVIRONMENT AND RESOURCES

Will the scientific environment, resources, 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? For early-stage investigators, are there competitive start-up funds to support the candidate's independent research program?

10. STATEMENT OF SCIENCE OUTREACH AND ADVOCACY

FEEDBACK OPTIONAL, NOT TO BE FACTORED INTO 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?

11. BUDGET

NOT TO BE FACTORED INTO SCORING

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 percent effort of key personnel appropriate? Is there potential scientific 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.

12. COMPLIANCE STATEMENTS

NOT TO BE FACTORED INTO SCORING

- 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 the plans for conducting sub-analysis by group, data security and
 confidentiality, biohazards and data and safety monitoring adequate?
- 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.
- 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.
- 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.

13. HEALTH EQUITY APPLICATIONS ONLY: CANCER HEALTH EQUITY STATEMENT

The reviewer critique should include a summary of the targeted area(s) of health equity proposed, the study population, social determinates of health that will be explored (at least two), the level(s) of influence (individual, interpersonal, organizational, community, or public policy) being targeted and the anticipated contribution(s) their findings will have in achieving cancer health equity. Assess the degree to which this statement aligns with the ACS cancer health equity definition and how well the contents of this statement are integrated in the research plan.

14. ALIGNMENT WITH RFA SCIENTIFIC SCOPE

IF APPLICABLE, evaluate the alignment of the application with the intent and scientific scope of the RFA.

AHEAD-DBG: Innovation, whether technological and/or conceptual, is a critical component for AHEAD DBG applications. Does the pilot project focus on bringing technologies to individuals rather than requiring travel to health care facilities in an innovative way? Innovative strategies could include breaking new ground or exploring a new application for an existing technology or intervention.

MISSION BOOST GRANT

INSTRUCTIONS

1. APPLICATION TEMPLATES

An application consists of several sections that must be uploaded before the online 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 5 pages.** Follow the formats and instructions as provided by the NIH.

4. REPLY TO PREVIOUS REVIEWS (PAGE 3.1)

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

All resubmissions must create a new application on ProposalCentral. Note: Only one resubmission is allowed for Mission Boost Grant applications.

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, underline type, etc.). **This section should not exceed 3 pages.**

5. PREVIOUS CRITIQUES (resubmissions only)

For applications submitted before Spring 2021, 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. If you are resubmitting a grant that was reviewed in Spring 2021 or later, go to the "Submitted" page, select "View Review Info," click "Print" to save it as a .pdf. Upload the document to your new application with the other proposal sections.

6. RATIONALE AND RESEARCH PLAN (PAGE 4.1)

Stage I

- **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 and Approach.** Briefly describe the research program for Stage I MBG funding and the approach(es) that will be utilized.

- **3. Innovation and Opportunity.** Describe the expected innovation, major risks, and opportunities of the research project and how you will meet the criteria of high risk/high reward.
- **4. Milestones**. Provide clear, quantitative, and outcome-based milestones for Stage I and describe how accomplishing the outcomes will enable clinical testing in Stage II. Milestones should not be a restatement of the Aims, but rather a breakdown of how the work will be accomplished and progress monitored.
- **C.** 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.
- **D.** Justification for Stage II funding (2 pages or less). Provide a brief overview of plans for clinical testing during Stage II. Review of your Stage II application is contingent upon achievement and review of Stage I milestones and outcomes.
- **E.** 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.

Stage II

- **A.** Rationale (500 words or less). What is the clinical need and how will this research project address that need?
- B. Research Plan (5 pages or less)
 - **1. Project Status.** Briefly summarize the current status of your Stage I project, including resulting presentations, publications, intellectual property, and funding.
 - **2. Milestone Accomplishments.** Describe the Milestones from your Stage I Mission Boost Grant, and the results demonstrating that you have achieved them.
 - **3. Goals and Approach.** Describe the research program for Stage II MBG funding and the approach(es) that will be utilized for clinical testing. This should include:
 - Trial design and data collection
 - Subject recruitment and eligibility
 - Compliance, adherence, and adverse effects
 - Expected results and potential difficulties
 - **4. Near-Term Clinical Benefits.** Briefly describe how this trial will benefit other cancer patients in the near-term (next 1-3 years).
- C. Clinical Approach Details (optional not to exceed 3 pages). This section is available if more in-depth descriptions of the clinical trial design, recruitment, or assays are needed to convey the specific approaches and procedures proposed.
- 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. BIOGRAPHICAL INFORMATION OF KEY PERSONNEL (PAGE 5.1)

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

8. 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 Scientific Directors 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 Pl's contribution to the project is covered by the other agency, no additional salary support for the Pl may be requested from the American Cancer Society.

Provide the following information separately for the PI and all other Key Personnel.

PIs are encouraged to develop collaborations with pharmaceutical companies or other private entities to help fund Stage II clinical trials if necessary.

- **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
 - 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. Role (e.g., PI, co-PI, co-I, etc.) and percent effort or person-months. For an active project, use person months, even if unsalaried, for the current budget period. Classify personmonths 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).
 - a. Source of funds
 - 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. Role (e.g., PI, co-PI, co-I, etc.) and percent effort or person-months. For an active project, use person months, even if unsalaried, for the current budget period. Classify personmonths 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 and 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. Details of the institutional commitment to support the applicant's salary and research.
 - b. A description of the space committed to the project.
 - c. The current term of the applicant's appointment.

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

Provide a list of collaborators and consultants, and then directly upload a 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.

10. 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. The institution is required to ensure IRB approval is obtained for the grant to start, and the approval documentation is uploaded into ProposalCentral within 3 months of grant activation.

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 biospecimens, 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.

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

IACUC approval must be obtained before animal work begins. An IACUC approval letter must be uploaded to ProposalCentral immediately upon approval.

Provide your rationale for using live vertebrate animals including the:

- Necessity for using the animals and species proposed;
- Appropriateness of the strains, ages, and genders of the animals to be used;
- 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 all biological and 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.

11. 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. For Stage II, the allowable budget is \$500,000 for 18 months plus 20% allowable indirect costs. Please complete the budget page located online at ProposalCentral. For applications submitted in April, use a start date of January 1 of the next year. For applications submitted in October, use a start date of July 1 of the next year.

A. 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 Principal Investigator (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. If a Key Person is not receiving salary, you can request \$0 for salary, but their percent effort is still required. Their effort and contribution to the project should be outlined in the Budget Justification even if they are not being compensated.

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 for 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.

Please note:

- See above for definitions of key personnel.
- 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 or
 other general-purpose equipment that will be used on multiple projects or for personal use
 are not allowable expenditures.
- C. **Supplies.** Group into major categories (glassware, chemicals, radioisotopes, survey materials, animals).
- D. **Travel.** Any foreign travel requires **pre-approval** by your Scientific Office. Domestic travel expenses do not require pre-approval.

- 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 direct costs in the online budget detail page on ProposalCentral. Each subcontract should be listed separately. 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's name in the "describe attachment" box.

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 costs allowance of up to 20% of the direct costs, excluding permanent equipment. For subcontracts, 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. If a subcontract is receiving indirect costs, list the indirect costs for each institution separately in the indirect costs section of the budget form.

Example: Stage I Budget Indirect Costs Year 1

Primary Institution Indirect	20% primary institution direct cost total
Subcontract 1 Indirect	20% subcontract 1 direct cost total
Subcontract 2 Indirect	20% subcontract 2 direct cost total
Total Indirect Costs	\$20,000 IDC

Note: Applicants should not budget above or below the allowable indirect cost rate.

H. Total Amount Requested. For Stage I, budget totals should reflect a maximum duration of 2 years. The total maximum budget may not exceed \$240,000 (\$100,00 per year direct plus \$20,000 per year indirect). For Stage II, budget totals should reflect a maximum duration of 18 months. The total maximum budget may not exceed \$600,000 (\$500,000 direct plus \$100,000 indirect). The amount on the application Title Page should match the total costs in the detailed budget section.

Note: For budgets that do not request the maximum allowable amount, if the grant is funded, the ACS will round the total to the nearest thousand dollars. We encourage applicants to request a budget amount that is rounded to an even thousand dollars.

12. 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.

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.

REVIEWER GUIDELINE CRITERIA

1. ALIGNMENT WITH ACS RESEARCH PRIORITY AREAS

Has the applicant identified and appropriately justified how their project fits within one or more ACS research priority areas?

2. CANDIDATE

Evaluate the candidate's academic, clinical, scientific qualifications. Assess the qualifications of the applicant giving consideration to the following items: goals and commitment to cancer-related research, productivity, support, collaborators, and overall appropriateness of candidate for the Stage I or Stage II MBG.

Stage I Mission Boost Reviewer Guidelines

3. REPLY TO PREVIOUS REVIEWS

If applicable, detail the candidate's responsiveness to previous critiques, focusing on the strengths and weaknesses of their reply.

4. RESEARCH PLAN

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.

5. STATUS OF PREVIOUS ACS PROJECTS

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

6. 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 in the near-term and long-term?

7. 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?

8. APPROACH

Will the planned approaches accomplish the project goals? 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?

9. MILESTONES

Will accomplishing the milestones enable clinical testing in a Stage II MBG?

10. 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?

11. JUSTIFICATION FOR SECONDARY BOOST

Evaluate the overall justification for Stage II. Will accomplishing the goals of Stage I allow clinical testing in Stage II?

Stage II Mission Boost Grant Reviewer Guidelines

3. REPLY TO PREVIOUS REVIEWS

If applicable, detail the candidate's responsiveness to previous critiques, focusing on the strengths and weaknesses of their reply.

4. RESEARCH PLAN

It is critical to evaluate rather than summarize the research plan. The research plan must be fundamentally sound, innovative and reduce the risks of studying a new drug, device, or procedure in patients.

5. STATUS OF PHASE I PROJECT

Comment on the productivity of the principal investigator during their Stage I grant.

6. MILESTONE ACCOMPLISHMENTS

Has the investigator accomplished their stated milestones? If not, have they explained why and how results from Stage I indicate that a Stage II is warranted?

7. GOALS AND APPROACH

Does the project address an important clinical problem or a critical barrier to clinical progress? Will the planned approaches accomplish the project goals? Are the clinical 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? Are potential difficulties and expected results discussed? Is the research timeline realistic?

8. NEAR-TERM CLINICAL BENEFITS

If the aims of the project are achieved, how will clinical practice improve? How will successful completion of the aims change clinical practice in the near-term and long-term?

9. 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?

12/10. BUDGET

NOT TO BE CONSIDERED IN SCORING

Evaluate the budget for Stage I/Stage II. 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? Does the PI have commitments from pharmaceutical companies or other private entities that will support the work? 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. Pls are encouraged to obtain institutional, industry and/or private funding to help support clinical trials if necessary.

13/11. COMPLIANCE STATEMENTS

NOT TO BE CONSIDERED IN SCORING

- **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 the plans for conducting sub-analysis by group, data security and confidentiality, biohazards and data and safety monitoring adequate?
- 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.
- **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.
- **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

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

1. COVER PAGES

Complete all fields, which include mandatory e-signature for the principal investigator. We provide text boxes for e-signatures for the departmental chair (or equivalent) and institutional officials to accommodate institution-specific requirements for proposal submissions, but neither is required for submission to ACS. Note: the PI must enable other users' access to the application on ProposalCentral to permit their e-signatures. If you have received a letter from the ACS Eligibility Committee, indicate that on the Table of Contents and upload the correspondence in the Appendix. See Part A General Instructions for more details.

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 2 pages.**

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

In 3 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 grant beyond previous experiences. 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. In addition, please provide all post-doctoral research experience in the Mentored Training section, which was added to the template. **Note: The Biographical Sketch may not exceed 5 pages.**

6. LIST OF RECOMMENDERS (PAGE 4.1)

List the name, title, and email address of three persons, <u>other than your proposed mentor(s)</u>, 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 uploaded 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 and upload to ProposalCentral

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, figures or tables 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 3 pages.

8. PREVIOUS CRITIQUES (resubmissions only)

For applications submitted before Spring 2021, 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. If you are resubmitting a grant that was reviewed in Spring 2021 or later, go to the "Submitted" page, select "View Review Info," click "Print" to save it as a .pdf. Upload the document to your new application following the Reply to Previous Review section.

9A. RESEARCH PLAN AND ENVIRONMENT (PAGE 6.1)

The same proposal may be submitted to other 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.

The total length of the RESEARCH PLAN section should not exceed 13 pages. 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 (I).

- **A. Specific Aims** (not to exceed 1 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 specific aims, 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 (3 pages or less). 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 Science Outreach and Advocacy (not to exceed 1 page). 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 to save lives, celebrate lives, and lead the fight for a world without cancer. 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.
- I. 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 (E).

9B. RESEARCH PLAN AND ENVIRONMENT: Use this outline if you are applying to the Priority Area Focused on Cancer Health Equity.

The same proposal may be submitted to other 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.

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 social determinants of health.

The total length of the RESEARCH PLAN section should not exceed 13 pages. 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 (I).

- **A. Specific Aims** (not to exceed 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 specific aims, 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 large 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 (3 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 Science Outreach and Advocacy (not to exceed 1 page). 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 to save lives, celebrate lives, and lead the fight for a world without cancer. 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.
- **I.** 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 (E).

10. DETAILED BUDGET

Please complete the budget page located online at ProposalCentral. For applications submitted in April, use a start date of January 1 of the next year. For applications submitted in October, use a start date of July 1 of the next year.

A. Personnel. Names and positions of all Key Personnel must be individually listed, and the percentage of time 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 a Key Person is not receiving salary, you can request \$0 for salary, but their percent effort is still required. Their effort and contribution to the project should be outlined in the Budget Justification even if they are not being compensated.

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: See above for definitions of key personnel.

Mentor(s): List all mentor(s), defined as those individuals who will provide guidance, support and mentoring to you on this award; \$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 or other general-purpose equipment that will be used on multiple projects or for personal use are not allowable expenditures.

- C. **Supplies.** Group into major categories (e.g., glassware, chemicals, radioisotopes, survey materials, animals).
- D. **Travel.** Any foreign travel requires **pre-approval** by your Scientific Office. Domestic travel expenses do not require pre-approval.

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 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 direct costs on the online budget detail page on ProposalCentral. Each subcontract should be listed separately. 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. If there is a subaward(s), 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.

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 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. If a subcontract is receiving indirect costs, list the indirect costs for each institution separately in the indirect costs section of the budget form.

Example: Budget Indirect Costs Year 1

Primary Institution Indirect	20% primary institution direct cost total
Subcontract 1 Indirect	20% subcontract 1 direct cost total
Total Indirect Costs	\$10,800 IDC

Note: Applicants should not budget above or below the allowable indirect cost rate.

H. **Total Amount Requested.** Budget totals should reflect a duration of 3-5 years (depending on the project period). The allowable per year direct cost is \$135,000 per year and the indirect costs rate is 8% (\$10,800 max per year), making the total cost per year cap \$145,800. The amount on the application Title Page should match the total costs in the detailed budget section.

Note: For budgets that do not request the maximum allowable amount, if the grant is funded, the ACS will round the total to the nearest thousand dollars. We encourage applicants to request a budget amount that is rounded to an even thousand dollars.

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 ACS 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*. Scientific Directors 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 Pl's contribution to the project is covered by the other agency, no additional salary support for the Pl may be requested from the American Cancer Society.

Provide the following information separately for the PI 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 ACS). Provide for each award:
 - a. Source of funds
 - 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. Role (e.g., PI, co-PI, co-I, etc.) and 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 ACS).
 - a. Source of funds
 - 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. Role (e.g., PI, co-PI, co-I, etc.) and 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 one award if both are approved for funding. The ACS 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 and could interfere with the Pl's budgeted effort on the ACS proposal, or could compromise CSDG eligibility (i.e., an NIH K-award or an R01 or R01-like grant as Pl at the time of application).

C. Institutional Support. Provide the following information for the PI only:

- a. Details of the institutional commitment to support the applicant including protected time, salary support and other financial resources, administrative support and available space.
- b. The current term of the applicant's appointment.
- c. Describe resources available to support the successful research career development of the applicant.

Documentation should be included in the Faculty or Scientific Appointment of Candidate (Section 14, below) written by the Department Chair. **There is no requirement that the PI have start-up funds or independent laboratory space.**

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, the amount of protected time for clinical researchers, administrative support, core facilities, institutional faculty development, research training, resources to support coursework or travel or other resources to foster the successful career development of the applicant. The letter should also describe the Department's long-term goals for the applicant's career.

PART II – TRAINING AND MENTORING PLAN

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

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. 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. Limit this section to 5 pages.

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 5 pages.

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

A letter of commitment must be provided from each mentor. The letter should include an 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.

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 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. The institution is required to ensure IRB approval is obtained for the grant to start, and the approval documentation is uploaded into ProposalCentral within 3 months of grant activation.

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 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 biospecimens, 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

IACUC approval must be obtained before animal work begins. An IACUC approval letter must be uploaded to ProposalCentral immediately upon approval.

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.

Biohazards

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

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.

Cancer Health Equity Research Statement (750 words limit)

Applicants proposing health equity research must upload a Cancer Health Equity Statement (**Page 14.3**). 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.

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.

For Health Equity applications submitted to the Clinical and Cancer Control Research Program there are additional criteria that need to be considered. Please ignore these criteria if the application you are reviewing is not a Health Equity Application.

Priority Focus on Health Equity Research in the Clinical and Cancer Control Research Program

Reviewers will assess the potential impact of the proposed research in advancing cancer health equity, if the specific aims are successfully accomplished. Applicants are instructed to compose their research question, background and significance, cancer relevance, innovation, approach and cancer health equity statement using the following terms and concepts.

For each section, focus on the strengths and weaknesses. Your final score should align with your written critique.

1. ALIGNMENT WITH ACS RESEARCH PRIORITY AREAS

Has the applicant identified and appropriately justified how their project fits within one or more ACS research priority areas?

2. CANDIDATE

Evaluate the qualifications of 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. There is no requirement that the PI have start-up funds or independent laboratory space.

Letters of Recommendation:

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 in the Critique Summary section of the webform template. This section will not be shared with the applicant.

3. REPLY TO PREVIOUS REVIEWS [IF APPLICABLE]

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

4. RESEARCH PLAN

Please provide a brief overview of the project. 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.

5. RESEARCH PLAN - SIGNIFICANCE AND CANCER RELEVANCE

Does the project address an important problem or a critical barrier to progress in the field? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or interventions that drive this field? How is this research relevant to persons at risk for, or living with, cancer and their family members and/or caregivers and friends?

For Health Equity Applications also consider: Does the project address an important problem or a critical barrier to progress in the field of cancer health equity? Has the investigator clearly indicated two or more social determinants of health they assess to be root causes of health disparities or inequities in some aspect of the cancer control continuum? How will the findings impactfully change concepts, methods, technologies, treatments, services, or interventions that drive this field? Your overall impact rating should reflect how this research will either: (1) substantially improve equity in access to cancer prevention, early detection, diagnosis, palliative care, treatment services or survivorship; (2) accelerate efforts to reduce cancer burden or costs, improve quality of care, delivery of care or quality of life; or (3) impact of public policy to advance health equity relevant to cancer? How is this research relevant to persons at risk for, or living with, cancer and their family members and/or caregivers and friends? Will this research inform strategies to address structural societal barriers (economic, political or social) that influence health or the ability to access or receive highquality care?

6. RESEARCH PLAN - 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?

For Health Equity Applications also consider: How does this research challenge or seek to shift current understanding of social, economic, political, research, or clinical practice paradigms in relation to health equity. Will any novel theoretical concepts, models, methodologies, technologies,

or interventions be developed or utilized to provide meaningful improvements or address critical needs or gaps?

7. RESEARCH PLAN - CANDIDATE/RESEARCH TEAM

Does the PI and research team (including mentor(s)) 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?

For Health Equity Applications also consider: Does the PI and research team (including mentors if applicable) 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? Is there adequate health equity expertise on the research team or mentoring team?

8. RESEARCH PLAN - APPROACH

Are the hypothesis and aims appropriate for answering the research question? Are the overall strategy, methodology, analyses and timeline well-reasoned and appropriate to accomplish the specific aims of the project? 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, and will particularly risky aspects be managed?

For Health Equity Applications also consider: Are the hypothesis and specific aim(s) appropriate for answering the cancer health equity research question? Is the research framed in the context of the ACS cancer health equity definition and in the context of at least two social determinants of health? Is the overall strategy, methodology, data collection, analyses and timeline well-reasoned and appropriate to accomplish the specific aims of the project? 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, and will particularly risky aspects be managed? For large multilevel studies, does the research plan incorporate two or more social determinants of health and two or more levels of influence (individual, interpersonal, organizational, community, or public policy)? Is it clear how the finding will contribute to achieving health equity?

9. RESEARCH PLAN - ENVIRONMENT AND RESOURCES

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?

10. BUDGET

NOT TO BE CONSIDERED IN SCORING

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 budget items justified, specified, and accurate? Is the project duration and PI percent effort (**minimum of 50%**) appropriate? Is there a potential overlap with the PI's other funded research? Describe any suggested budget changes (i.e.,

could relate to personnel, research material and/or animals). Use specific amounts and/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.

11. TRAINING AND MENTORING PLAN

Assess the appropriateness of the proposed core curriculum, courses, and lectures in enhancing the research training of the applicant, and their relevance to the applicant's career objectives.

12. INSTITUTIONAL RESOURCES AND ENVIRONMENT FOR TRAINING

Evaluate the appropriateness of the environment (academic and research) for the proposed training program. Include departmental and other institutional personnel, ongoing research and other relevant activities, facilities, resources, access to any populations or individuals to be studied, relevant collaborative relationships, etc. Reference any relevant accreditation from professional societies or organizations. Describe how access to these resources will directly benefit the candidate.

13. TRAINING EXPERIENCE, BIOSKETCH(ES), SUPPORT, AND COMMITMENT LETTER(S) 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 mentor(s) in cancer research and in training cancer researchers, the commitment of mentor(s) to the plan, and the overall appropriateness of the mentor(s) and mentor(s) qualifications for the proposed research project.

14. COMPLIANCE STATEMENTS

NOT TO BE CONSIDERED IN SCORING

- 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 the plans for conducting sub-analysis by group, data security and
 confidentiality, biohazards, and data and safety monitoring adequate?
- **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.
- Vertebrate Animals. The peer review committee will evaluate the involvement of live, vertebrate animals as part of the scientific assessment according to the following points: 1) Necessity for the use of the animals and species proposed; 2) Appropriateness of the strains, ages, and gender of the animals to be used for the experimental plan proposed; 3) Justifications for, and appropriateness of, the numbers used for the experimental plan proposed.
- 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.

15. HEALTH EQUITY APPLICATIONS ONLY: CANCER HEALTH EQUITY STATEMENT

The reviewer critique should include a summary of the targeted area(s) of health equity proposed, the study population, social determinates of health that will be explored (at least two), the level(s) of influence (individual, interpersonal, organizational, community, or public policy) being targeted and the anticipated contribution(s) their findings will have in achieving cancer health equity. Large

multilevel health equity proposals must include two or more levels of influence. Assess the degree to which this statement aligns with the ACS cancer health equity definition and how well the contents of this statement are integrated in the research plan.

POSTDOCTORAL FELLOWSHIP INSTRUCTIONS

PART I - ADMINISTATIVE INFORMATION, CANDIDATE, RESEARCH PROJECT

1. COVER PAGES

Complete all fields, which include mandatory e-signatures for the principal investigator and primary mentor. We provide text boxes for e-signatures for the departmental chair (or equivalent) and institutional officials to accommodate institution-specific requirements for proposal submissions, but neither is required for submission to ACS. Note: the PI must enable other users' access to the application on ProposalCentral to permit their e-signatures. 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)

Indicate the appropriate page number for the start of each section. At the bottom of the template, list the documents in the Appendix. Section must not exceed 2 pages.

4. BUDGET

Please complete the budget page located online at ProposalCentral. Stipends for Postdoctoral Fellowships are \$66,000, \$68,000, and \$70,000 for the first, second, and third years respectively. Fellows submitting two-year projects may request progressive stipends of \$68,000 and \$70,000, respectively. For applications submitted in April, use a start date of January 1 of the following year. For applications submitted in October, use a start date of July 1 of the following year.

Each fellow will receive a **yearly allowance of \$4,000** to be used to benefit the fellow (i.e., health insurance, workshop costs, career development activities, attending scientific meetings, etc.). In the last year of funding, a \$1,500 **travel allowance** is to be prioritized for travel costs to attend and present at the biennial ACS Jiler Professors and Fellows Conference, if offered that year, or expenses to present at a domestic scientific meeting of choice. **Institutional indirect costs may not be recovered from these funds.** No allowance funds may be used for any international activities.

Example Budgets

	3-Year Fellowship			2-Year Fellowship		
Period	Year 1	Year 2	Year 3	Year 1	Year 2	
Stipend	66,000	68,000	70,000	68,000	70,000	
Allowance	4,000	4,000	4,000	4,000	4,000	
Travel			1,500		1,500	
Total	\$217,500			\$147,500		

5. 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. Please notify the Scientific Director immediately if you accept an award from another agency.

6. BIOGRAPHICAL SKETCH OF APPLICANT (PAGE 3.1)

Complete the NIH Biosketch template, following the format and instructions provided by the NIH. In addition, please provide all post-doctoral research experience in the Mentored Training section, which was added to the template. **Note: The Biographical Sketch may not exceed 5 pages.**

7. 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.**

8. PREVIOUS CRITIQUES (resubmissions only)

Previous critiques must be included with resubmissions. For resubmissions of applications reviewed before Spring 2021, 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. If you are resubmitting a grant that was reviewed in Spring 2021 or later, go to the "Submitted" page, select "View Review Info," click "Print" to save it as a .pdf, and then upload the critiques with your application.

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

In 3 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.

10A. FELLOWSHIP RESEARCH PLAN (PAGE 6.1)

The total length of this section should not exceed 9 pages, excluding 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.

- **A. Specific Aims.** List the objectives and goal of the research proposed and describe the specific aims briefly in order of priority.
- **B. 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.

- **C.** 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.
- **D. 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.
- **E. 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.

10B. HEALTH EQUITY RESEARCH PLAN- use this outline if you are applying to the Priority Area Focused on Cancer Health Equity

Key Words and Definitions

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.

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

The total length of this section should not exceed 9 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. Applicants are at liberty to include a narrative describing the theoretical underpinning of the research plan using one or more theoretical models

- **A. 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.
- **B. 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.
- **C. 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.
- D. 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.

E. 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.

11. STATEMENT OF SCIENCE OUTREACH AND ADVOCACY (PAGE 7.1)

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 to save lives, celebrate lives, and lead the fight for a world without cancer. 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. **Do not exceed one page**.

12. LETTERS OF RECOMMENDATION (8.1)

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, <u>your recommenders must upload the letters on ProposalCentral again.</u>

PART II - TRAINING AND MENTORING PLAN

The sections 13-16 must be prepared by the primary mentor (even if there are co-mentors).

13. PROPOSED TRAINING AND MENTORING (PAGE 9.1)

In 3 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. 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.

14. FACILITIES AVAILABLE (PAGE 10.1)

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

15. 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 5 pages.

16. RESEARCH 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.

17. 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. The institution is required to ensure IRB approval is obtained for the grant to start, and the approval documentation is uploaded into ProposalCentral within 3 months of grant activation.

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), and 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 biospecimens, 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.

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

IACUC approval must be obtained before animal work begins. An IACUC approval letter must be uploaded to ProposalCentral immediately upon approval.

Provide your rationale for using live vertebrate animals including the:

- Necessity for using the animals and species proposed.
- Appropriateness of the strains, ages, genders of the animals to be used.
- 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 and chemical hazards, if applicable.

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
- 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.

Cancer Health Equity Research Statement (750-word limit)

Applicants proposing health-equity research must upload a Cancer Health Equity Statement (**Page 13.3**). 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.

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
- quality of care, quality of life, or health policy impact

18. 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 encouraged 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.

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.

For Health Equity applications submitted to the Clinical and Cancer Control Research Program there are additional criteria that need to be considered. Please ignore these criteria if the application you are reviewing is not a Health Equity Application.

Priority Focus on Health Equity Research in the Clinical and Cancer Control Research Program

Reviewers will assess the potential impact of the proposed research in advancing cancer health equity, if the specific aims are successfully accomplished. Applicants are instructed to compose their research question, background and significance, cancer relevance, innovation, approach and cancer health equity statement using the following terms and concepts.

For each section, focus on the strengths and weaknesses. Your final score should align with your written critique.

1. ALIGNMENT WITH ACS RESEARCH PRIORITY AREAS

Has the applicant identified and appropriately justified how their project fits within one or more ACS research priority areas?

2. 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 part of a team, and personal characteristics. To maintain confidentiality, please include this evaluation in the "Critique Summary" section of the webform so this information will not be released to 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.

3. REPLY TO PREVIOUS REVIEWS [IF APPLICABLE]

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

4. PLANS FOR WORK UNDER FELLOWSHIP

Provide a brief overview of the project. 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.

5. RESEARCH PLAN - SIGNIFICANCE AND CANCER RELEVANCE

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? 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.

For Health Equity Applications also consider: Does the project address an important problem or a critical barrier to progress in the field of cancer health equity? Has the investigator clearly indicated two or more social determinants of health they assess to be root causes of health disparities or inequities in some aspect of the cancer control continuum? How will the findings impactfully change concepts, methods, technologies, treatments, services, or interventions that drive this field? Your overall impact rating should reflect how this research will either: (1) substantially improve equity in access to cancer prevention, early detection, diagnosis, palliative care, treatment services or survivorship; (2) accelerate efforts to reduce cancer burden or costs, improve quality of care, delivery of care or quality of life; or (3) impact of public policy to advance health equity relevant to cancer? Will this research inform strategies to address structural societal barriers (economic, political, or social) that influence health or the ability to access or receive high-quality care?

6. RESEARCH PLAN - 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? How will particularly risky aspects be managed?

For Health Equity Applications also consider: Are the hypothesis and specific aim(s) appropriate for answering the cancer health equity research question? Is the research framed in the context of the ACS cancer health equity definition and in the context of at least two social determinants of health? Is the overall strategy, methodology, data collection, analyses and timeline well-reasoned and appropriate to accomplish the specific aims of the project? 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, and will particularly risky aspects be managed? For large multilevel studies, does the research plan incorporatetwo or more social determinants of health and two or more levels of influence (individual, interpersonal, organizational, community, or public policy)? Is it clear how the finding(s) will contribute to achieving health equity?

7. PLANS FOR WORK UNDER FELLOWSHIP – 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? Has the research team previously collaborated on research or publications? If not, are members of the proposed study team appropriate to carry-out the research?

For Health Equity Applications also consider: Is there adequate health equity expertise on the research team or mentoring team?

8. PLANS FOR WORK UNDER FELLOWSHIP - 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?

9. PLANS FOR WORK UNDER FELLOWSHIP – STATEMENT OF SCIENCE OUTREACH AND ADVOCACY

FEEDBACK OPTIONAL; THIS SECTION IS NOT SCORED. 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?

10. PROPOSED TRAINING AND MENTORING PLAN

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.

11. 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 availability of these resources will directly benefit the candidate.

12. TRAINING EXPERIENCE, BIOSKETCH(ES), SUPPORT, AND COMMITMENT LETTER(S) 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. Consider the funding support of the mentor. This is critical because the budget for a PF award is predominantly stipend support.

13. COMPLIANCE STATEMENTS

NOT TO BE CONSIDERED IN SCORING

- 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 the plans for conducting sub-analysis by group, data
 security and confidentiality, biohazards, and data and safety monitoring adequate?
- 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.
- **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.
- **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.

14. HEALTH EQUITY APPLICATIONS ONLY: CANCER HEALTH EQUITY STATEMENT

Include a summary of the targeted area(s) of health equity proposed, the study population, social determinates of health that will be explored (at least two), the level(s) of influence (individual, interpersonal, organizational, community, or public policy) being targeted and the anticipated contribution(s) their findings will have in achieving cancer health equity. Large multilevel health equity proposals must include two or more levels of influence. Assess the degree to which this statement aligns with the ACS cancer health equity definition and how well the contents of this statement are integrated in the research plan.

RESEARCH PROFESSOR AND CLINICAL RESEARCH PROFESSOR INSTRUCTIONS

Program Contact: Kim Smith, Extramural Research Manager (kim.a.smith@cancer.org)

LETTER OF INTENT (LOI)

Interested applicants for the Professor Awards must first submit a 2-3-page letter of intent (LOI), a biographical table, and a *curriculum vitae* via ProposalCentral. The LOI should briefly describe the candidate's seminal contributions to cancer research, their leadership roles in the cancer research community, their track record of mentoring individuals who have become successful in cancer research. The biographical table should highlight scholarly achievement.

- The LOI for the Research Professor Award must be submitted between December 1 and February 1.
- The LOI for the Clinical Research Professor Award must be submitted between June 1 and August 1.

Candidates will be notified by email if their LOI is accepted or rejected. If the LOI is accepted, the candidate will then have access to all application materials in ProposalCentral.

APPLICATION

Research Professor candidates whose LOI was approved must submit their application by the April 1 deadline, and Clinical Research Professor candidates whose LOI was approved must submit their application by the October 15 deadline.

PART I

New applications must provide all the information requested in Templates 1.1 through 8.1.

Renewal applications 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 2 pages, including an itemized list of contents in the Appendix.

3. BIOGRAPHICAL INFORMATION OF APPLICANT (PAGE 2.1)

A. Personal Statement (not to exceed 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 and ongoing experimental work, technical expertise, collaborators, scientific environment, mentoring, and service.

B. Mentoring and Leadership (not to exceed 2 pages)

Describe how you have enhanced your field in your role as a mentor and leader. This may include information about your leadership and service at your institution and/or at the regional, national, or international levels. As a part of your description on mentoring, list the individuals you have trained, their current positions, and describe how your mentorship has facilitated and advanced their cancer research career development.

C. Contributions to Science (not to exceed 4 pages)

Describe your seminal contribution(s) that you and your research program have made to cancer research. A **seminal contribution** is defined as work led by the applicant that has created a new field, changed the direction of the research enterprise, or dramatically altered our understanding of the causes, prevention, detection, diagnosis, or treatment of cancer.

For each seminal contribution, provide: the historical background that frames the scientific problem, the central finding(s) of your research, 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.

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

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>awards</u>, <u>active</u> support, and all applications <u>pending</u> review. Give the name of the granting agency, grant number, project title, award 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 research program, strategic plans for the term of the award, and the impact your future research and clinical (if applicable) activities will have on your research field. This could also include plans to enhance research, mentoring, and/or patient services.

The research and research-related clinical activities proposed **should not** simply be a continuation of your current work. The strategic plans should describe an overview of strategies to advance your program of research and mentorship in novel ways that represent a creative and innovative use of funds leading to broader impact and reflecting the exceptional nature of this award.

Consider the following: What knowledge gaps in your field remain to be filled and/or what enhancements need to be implemented? 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.

Indicate the impact the Award would have on your program and outline how it 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?). The strategic plans you propose should clearly illustrate your potential for continuing to be a leader in the field in terms of the plans' 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.

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 three individuals from whom you have requested letters of recommendation. 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. 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

Sections 8 and 9 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., biographical table, key reprints, preprints, etc.) included in the Appendix should be listed in the Table of Contents (Page 1.1 of the application).

Biographical Table (Required)

Include the Biographical Table that was submitted with your Letter of Intent in the Appendix of your full application. The template is provided in the application materials.

RENEWAL APPLICATIONS ONLY

At the start of the renewal process, an LOI will be requested via ProposalCentral. Since this is a renewal, you do NOT have to submit a formal LOI. Enter the title of your renewal in the online LOI and submit it. You will then receive an email confirming access to the application forms on ProposalCentral.

The renewal application must be submitted electronically via ProposalCentral. Renewals must be submitted between January 1 and April 1 of the final year of the Research Professor Award, and between July 1 and October 15 of the final year of the Clinical Research Professor Award.

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

1. TABLE OF CONTENTS (PAGE 1.1) - For Renewal Award

The Table of Contents is pre-numbered and should be limited to 2 pages, including an itemized list of the contents of the Appendix.

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

This section should not exceed 6 pages.

- Articulate your strategic vision of how you will continue to advance your research discipline for the next five years.
- Identify the top challenges in the field and the novel and innovative approaches you will use to address them.
- 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.).
- 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 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.

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 (3-page limit)

Summarize the specific aims and your progress to date.

C. Outputs

- 1. Oral presentations: Provide the conference name or venue 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. Please bold the publications where ACS was acknowledged.
- 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 because of your research program.
- 6. Other (specify)

D. Mentoring (3-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 your mentorship has facilitated and advanced their cancer research career development.

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 for each: the grant title, number, granting institution, award amount, and award term.

H. Recognitions and Awards

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

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

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).

Biographical Table (Required)

Include an updated Biographical Table in the Appendix of your full application. The template is provided in the application materials.

REVIEWER GUIDELINE CRITERIA

Evaluation of New Research Professor/Clinical Research Professor Applications

For each section, focus on the strengths and weaknesses. Your final score should align with your written critique.

1. OBJECTIVE

Briefly describe the overarching goal(s) of the research program and the general aims and potential impact of the proposed project.

2. INVESTIGATOR

Has the applicant made at least one seminal contribution to their field (a key requirement for consideration of this award)? If so, assess the impact, to date, of the contribution or contributions. Is the investigator regarded as a "thought leader"? Is the applicant continuing to be a leader in their area(s) of expertise? Are their contributions more intellectual or technical in nature? Does the investigator have a track record of high-impact publications and awards? Is the investigator a leader in the cancer research community? Consider the content of the Letters of Recommendation and the summary table of scholarly successes in the Appendix when critically evaluating the applicant.

3. RESEARCH PROGRAM

Evaluate the significance, cancer relevance, and novelty of the investigator's overall research program. Has the applicant identified and adequately justified the seminal contribution(s) that their research program has made to cancer research? In what innovative way(s) is the applicant's cancer research program addressing a critical unmet need? Does this program have a likelihood of continued high impact discoveries for cancer research?

4. STRATEGIC PLAN

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. Evaluate the significance, cancer relevance, and novelty of the proposed strategic plan. Has the applicant identified an unmet need or gap in the field, and will their strategic plan fill the void? Does the proposed project explore a new concept (technically and/or conceptually) rather than a continuation of current investigations? Is the applicant proposing a creative use of the discretionary funds? Are there other investigators doing similar work? In the case of Clinical Research Professor applications, a clinical component should be included. Has the applicant adequately articulated their vision for advancing their research discipline in the next 5 years? Will this vision advance scientific knowledge or aspects of clinical practice for cancer and cancer patients?

5. MENTORSHIP

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 or junior faculty members who have been promoted and/or tenured. Mentoring may also be demonstrated through educational/training activities. Does the investigator have a track record of mentoring trainees who have gone on to be successful in research? Is there evidence of a current commitment to mentoring?

6. SERVICE

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. 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. Will the applicant be a strong representative of and spokesperson for the American Cancer Society?

Evaluation of Renewal Research Professor/Clinical Research Professor Applications:

For each section, focus on the strengths and weaknesses. Your final score should align with your written critique.

1. OVERVIEW

The renewal should focus on both the project as funded along with their entire research program. Briefly describe the overarching goal(s) of the research program and the general aims and potential impact of the proposed strategic plan.

2. RESEARCH PROGRAM AND PROPOSED PROJECT

Briefly describe the Professor's major research accomplishments over the past 5 years. Evaluate the Professor's strategic vision for how they will continue to advance their research discipline for the next five years. How well do they identify the top challenges in the field and what novel and innovative approaches they will use to address them? Evaluate their productivity and their continued leadership in their field. Do they continue to be a "thought leader" in the field of study?

3. MENTORING AND SERVICE

Evaluate the Professor's continued commitment to mentoring. Assess the Professor's service to the cancer community, with particular emphasis on their role as a spokesperson for the ACS and the ACS research program the past five years.

APPENDIX A: EXAMPLES OF GENERAL AUDIENCE SUMMARIES

Note: Some grant mechanisms do not require General Audience Summaries. If required for the application, there will be a field for the General Audience Summary on ProposalCentral.

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. Developmental 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: EXAMPLE OF STRUCTURED TECHNICAL ABSTRACT

Title: 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: EXAMPLES OF PROJECT ALIGNMENT TO RESEARCH PRIORITIES

Example 1

Epiluminescent microscopy is used for the clinical evaluation of pigmented skin lesions, including early-stage melanoma. However, several common benign skin conditions can sometimes exhibit hyperpigmentation leading to unnecessary surgical excision. We have recently discovered that amplification of gene X is associated with early-stage melanoma. Based on encouraging preclinical validation, we propose to develop a non-invasive, light-based companion diagnostic assay to identify early-stage melanoma (i.e., during an annual skin exam). This concept, which is technically and conceptually innovative, highly aligns with the ACS priority area screening and early detection.

Selection of Priorities

Screening and Diagnosis: 100%

Example 2

The focus of this investigation is to elucidate how cancer stem cells in triple negative breast cancers resist chemotherapies with the goal of developing new strategies for anti-cancer drug design (Treatment as the primary priority). The mechanistic insights we glean from the ability of cancer stem cells to continuously self-renew could also lead to the development of improved prognostic and diagnostic markers (Screening and Diagnosis) as well as a better understanding of the cells that drive tumorigenesis and disease recurrence (Etiology).

Selection of Priorities

Etiology: 25%

Screening and Diagnosis: 25%

Treatment: 50%

Example 3

Underlying genetic mutations in leukemia cells are a significant factor in the risk and outcomes in childhood acute leukemia. One specific type of genetic mutation is found in multiple subtypes of acute leukemia associated with a poor prognosis. In this project, we will characterize this and other mutations in blood samples from acute leukemia patients in a large-scale study to identify potential markers that can be used to diagnose acute leukemia (Screening and Diagnosis). This analysis will also be used to identify proteins specific to acute leukemia that may be targeted therapeutically (Treatment).

Selection of Priorities

Screening and Diagnosis: 85%

Treatment: 15%

Example 4

Children with refractory or relapsed solid tumors remain essentially incurable with conventional chemotherapy and radiation, and the effects of these treatments are life threatening. Current "tumor-specific" treatments, such as infusion of natural killer immune cells, have had limited success. This project will use several approaches to improve refractory solid tumor by testing an antibody recognized neuroblastoma and osteosarcoma tumor cells. Success of any of these approaches will be a breakthrough for children with refractory or relapsed neuroblastoma and osteosarcoma.

Selection of Priorities

Treatment: 100%

Example 5

Prostate cancer (PCa) diagnosis and mortality rates are higher in African American (AA) men compared to Caucasian-American (CA) men. AA patients respond poorly to treatments, and the PCa tumors are more aggressive than those in CA patients. We have identified a cellular dysfunction in tumors from AA PCa patients that may contribute to treatment in AA patients. In this project we will screen AA PCa tumors for this dysfunction (Etiology) and determine if treatments that target the cellular dysfunction in AA PCa cells can help improve treatment outcomes for AA patients (Treatment).

Selection of Priorities

Etiology: 20% Treatment: 80% **Example 6**

Lung cancer survivors have a high symptom burden. Prior research has demonstrated that early palliative care improves quality of life. Cancer rehabilitation plays an important role in survivorship care by facilitating participation in daily living. This study involves collaboration between palliative care and cancer rehabilitation teams. We will compare a novel home-based intervention to in-person ambulatory rehabilitation and evaluate objective measures of pulmonary functioning, physical functioning, and health related quality of life. This aligns with the ACS survivorship priority.

Selection of Priorities

Survivorship: 100%

Example 7

ACS believes that everyone should have a fair and just opportunity to prevent, find, treat and survive cancer. Where you live and your income may impact the ability to receive high quality cancer care. Our preliminary data reveal that distance from a primary care provider impacts screening rates for breast, lung and colorectal cancer. To increase screening rates in a diverse group of low wage workers, we will test a culturally tailored worksite intervention for farm and poultry workers and use a waitlist control group. The social determinants of health we believe are drivers of differential screening outcomes include low socioeconomic status, inadequate health insurance coverage and low health literacy.

Selection of Priorities

Health Equity: 100%

Example 8

According to the ACS Facts and Figures, colorectal cancer (CRC) is the third most common cancer and third leading cause of death among men and women in the US. Trend data, especially over the last decade, reveals increased CRC incidence for individuals under the age of 50. This study aims to better understand the birth cohort effect and involves mixed methods to better understand factors associated with early onset CRC. Our findings will be used to inform a larger tailored intervention to improve early diagnosis of CRC under the age of 50 years. This aligns with the ACS research priority for screening and diagnosis.

Selection of Priorities

Screening and Diagnosis: 100%

APPENDIX D: CLASSIFICATION CATEGORIES - AREAS OF RESEARCH

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

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

Applicants are asked to select from the following codes:

1 - BIOLOGY

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

1.1 Normal Functioning

Examples of science that would fit:

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

1.2 Cancer Initiation: Alterations in Chromosomes

Examples of science that would fit:

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

1.3 Cancer Initiation: Oncogenes and Tumor Suppressor Genes

Examples of science that would fit:

• Genes and signals involved in growth stimulation or repression, including oncogenes (Ras, etc.), and tumor suppressor genes (p53, etc.)

- Effects of hormones and growth factors and their receptors such as estrogens, androgens, TGF-beta, GM-CSF, etc.
- Research into the biology of stem cell tumor 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

Examples of science that would fit:

- Research into the role of lifestyle factors such as smoking, chewing tobacco, alcohol
 consumption, parity, diet, sunbathing, and exercise in the origin and cause of cancer or
 increasing the risk of cancer
- Research into the social determinants of cancer such as crime, housing dilapidation, (poor housing), neighborhood level, socio-economic 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 tumors

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

Examples of science that would fit:

• Informatics and informatics networks; for example, patient databanks

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

3 - PREVENTION

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

3.1 Interventions to Prevent Cancer: Personal Behaviors (Non-Dietary) that Affect Cancer Risk Examples of science that would fit:

- Research on determinants of personal behaviors, such as physical activity, sun exposure, and tobacco use, known to affect cancer risk and interventions (including educational and behavioral interventions directed at individuals as well as population-based interventions including social marketing campaigns, environmental supports, and regulatory, policy and legislative changes), to change determinants 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 Examples of science that would fit:

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

- Education of patients, health care providers, at-risk populations, and the general population about cancer risk and diet
- Communicating cancer risk of diet to underserved populations, at-risk populations, and the general public
- Communication of nutritional interventions that reduce cancer risk
- 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 body-based practices (e.g., spinal manipulation, massage therapy), and other practices (e.g., light therapy, traditional healing) used as preventive measures

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/personalized 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, cell-based 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/personalized 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

- 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

Examples of science that would fit:

- Epidemiology and end results reporting (e.g., SEER)
- Registries that track incidence, morbidity, co-morbidities/symptoms, long-term effects and/or mortality related to cancer
- Surveillance of established cancer risk factors in populations such as diet, body weight, physical activity, sun exposure, and tobacco use, 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

- 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

Examples of science that would fit:

- Development of generic health provider-patient communication tools and methods (e.g., telemedicine/health)
- Tailoring educational approaches or communication to different populations (e.g., social, racial, geographical, or linguistic groups)
- Research into new educational and communication methods and approaches, including special approaches and considerations for underserved and at-risk populations
- Research on new methods and strategies to disseminate cancer information/innovation to healthcare providers (e.g., web-based information, telemedicine, smartphone apps, etc.) and the effectiveness of these approaches
- Research on new communication processes and/or media and information technologies within the health care system and the effectiveness of these approaches
- Media studies focused on the nature and ways in which information on cancer and cancer research findings are communicated to the general public
- Education, information, and assessment systems for the general public, primary care professionals, or policy makers
- Research into barriers to successful health communication

6.6 End-of-Life Care

Examples of science that would fit:

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

6.7 Research on Ethics and Confidentiality

Examples of science that would fit:

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

6.8 – Historical code [no longer used]

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

- 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.