



AMERICAN CANCER SOCIETY – FLATIRON CLINICAL TRIALS TECHNOLOGY RESEARCH IMPACT AWARD

APPLICATION INSTRUCTIONS EFFECTIVE APRIL 2025

ELECTRONIC APPLICATION DEADLINE: June 2, 2025

AMERICAN CANCER SOCIETY, INC.

Extramural Discovery Science

RFA Announcement: Link to Webpage

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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.

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I. GENERAL INFORMATION

Applicant use of generative AI tools: An applicant is responsible for all content in their application, including any content generated using an AI tool or large language model. The applicant should appropriately credit an AI tool used in the development of their application and appropriately cite the source of the content whenever possible. Applicants should follow any guidelines or regulations in place at their institution, and the use of AI tools cannot conflict with the ACS Guidelines for Research and Peer Review Integrity in the <u>Grant Policies</u>.

A. THE GRANT APPLICATION SYSTEM

Once your LOI is approved in ProposalCentral, an application will be automatically created in the active proposals section of your ProposalCentral account.

Electronic Submission Portal: Once you reach ProposalCentral, follow the instructions to login/register. Once logged-in, the application should be visible under the "Proposals" section.

a. The key steps for starting an application:

- Create Application Title: Click on "Edit," enter the same Project Title as the LOI Title, and click SAVE.
- **Save Application:** Once you have clicked on the "Save" button, the links to the other pages of the application appear in the Proposal Sections menu.
- **b. Enable Other Users to Access this Proposal:** Allow others (e.g., institutional administrators or collaborators) to view, edit, e-sign, or submit your proposal.
- **c. Technical Assistance:** Detailed information is available through tutorials provided on the ProposalCentral login page. If you have problems accessing or using the electronic application process, click on "Help" or contact ALTUM Customer Service at pcsupport@altum.com or 1-800-875-2562.

2. APPLICATION FORMAT

- Insert PI name in the header for each template of the application. Do not change the footers on the templates.
- **Type size:** Use 12-point Times New Roman or 11-point Arial as the minimum font size for the text of the application. A 10-point Times New Roman or 9-point Arial font type may be used for figures, legends, and tables.
- Applications may be single- or double-spaced (if single spacing, enter a space between paragraphs).
- **Margins:** ≥ 0.5 inches all around unless a form with different margins is supplied in the application templates.
- **Numbered Sections:** Number the pages in the 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.
- **NIH Biosketches:** Use the current NIH format for all NIH Biosketches. If the NIH has modified the NIH biosketch, applicants may use the newly modified template, or the template provided in ProposalCentral.

3. UPDATES OF INFORMATION

The following updates should be communicated as specified to the Scientific Director for the funding mechanism: joanne.elena@cancer.org.

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

Change of Address: Notify the program office by email if a mailing address, email address, or phone number has changed since submission. Include the PI and application number on the correspondence and update this information in ProposalCentral.

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

4. REQUIRED INFORMATION

Project Title: Do not exceed 150 characters including spaces; avoid abbreviations if possible. **Note:** The title will truncate after 81 characters on the formatted PDF 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 your Professional Profile before finalizing this section and submitting your application. Please keep all contact information current.

- Citizenship Status (mandatory): On ProposalCentral under "Professional Profile", indicate
 your current citizenship status and country of citizenship. Note that there are no citizenship
 restrictions for this award.
- **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.
- 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.

Institution and Contacts: Provide the required information for the PI's sponsoring institution and institution officials.

• MSI Designation: Indicate using the radio buttons whether the Pl'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 front page 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.
- 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 take place at a university. The TTO will be responsible for reporting all IP
 updates to the ACS should the project be awarded funding.
- **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.

Key Personnel: Defined as 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). Enter the required information for each Key Person, including their designated role. **The PI is always considered Key Personnel, but do not list them under Key Personnel on ProposalCentral.**

- Key Personnel can include individuals at the doctorate, master's, or baccalaureate level (such as postdoctoral fellows, graduate students, and research assistants) if they meet this definition.
- Key Personnel are personnel that give >0% effort to the project, even if they are not being compensated.

Key Personnel Roles and Definitions

- The **Principal Investigator** assumes the authority and responsibility to direct the project. The ACS does not permit applications to be directed by Co-Principal Investigators.
- A Co-Investigator is a vital scientific contributor (at the same or a different institution), often bringing a needed expertise to the research team. This person commits some level of measurable effort to the project and is therefore Key Personnel, whether compensated or not.
- A **Collaborator** plays a lesser role in the thinking and logistics of the project than a Collaborator. Depending on the role and effort, a collaborator may be designated as Key Personnel and may be compensated.
- A Consultant provides expert advice most often for a fee. If the consultant contributes to the scientific development or execution of a project substantively and measurably, he or she should be designated as Key Personnel.
- Other is defined as individuals who are compensated for their contribution to the project but are not considered Key Personnel (e.g., student assistants, technical staff).

The table below provides information about the documents required for each personnel class.

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	Letter of
Collaborator	No	No	No	No	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

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

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 community research partners, ACS staff members, potential donors, and the public.

- Community research partners are individuals without formal scientific or medical training
 who are full voting members of peer review panels. The community research partner 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.
 Therefore, 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.

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

The structured technical abstract is a summary of the proposed research or scholarly project for **general scientific** audiences. Organize the abstract into the following sections:

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

^c If key personnel are not being paid, percent effort is still required. Note that the percent effort indicated in the budget section in ProposalCentral can be different than requested compensation.

- 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 the program office if you do not wish to have your abstract utilized in this manner.

7. STATEMENT OF CANCER RELEVANCE AND IMPACT

This section should be written for a non-scientific audience. **Avoid the use of technical jargon.** This form is limited to **1500 characters**, including spaces.

In this statement, describe how the project may ultimately contribute to the control of cancer and 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, and survive cancer. Where applicable, explain how this work may inform public health recommendations, policy, and/or clinical care guidelines.

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. This section is limited to **1500 characters**, including spaces. Note: If the character limit is exceeded in this section, which is evaluated, it will be truncated.

9. SELECTION OF RESEARCH PRIORITY AREAS

Select the research priority area or areas 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 CTTRIA Policies document (pages 3-4).

10. PROJECT CODING: CSO CODES AND CANCER TYPES

Note: Project coding is not considered at peer review. Red asterisks indicate required fields.

Donors often have an interest 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 ACS 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.

Applicants must also select the type(s) of cancer of relevance to the project; up to 5 cancer types may be selected.

11. ASSURANCES AND CERTIFICATION

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

The institution is responsible for the accuracy, validity and conformity with the most current institutional guidelines for all administrative, fiscal and scientific information in the application. The Institution may be liable for the reimbursement of funds associated with any inappropriate or fraudulent conduct of the project activity.

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

12. PI DATA SHEET

The PI demographic information is for use by the Extramural Discovery Science department. While "choose 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 in DEI and identify areas that need improvement.

13. APPLICATION SUBMISSION AND REQUIRED E-SIGNATURE

- 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 Monday, June 2, 2025. Because the Summer application deadline of June 1 falls on a weekend, 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: You will not be able to make any changes to the forms or upload any modifications to the files after submission.

II. APPLICATION TEMPLATES

The application templates for each section are available on ProposalCentral. The templates must be downloaded and completed offline. Completed templates must be converted into PDF documents before uploading to the corresponding application sections.

1. TABLE OF CONTENTS (PAGE 1.1)

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

2. BIOGRAPHICAL SKETCH OF APPLICANT (PAGE 2.1)

Provide a Biosketch for the applicant. Follow the formats and instructions provided by the NIH. The biographical sketch may not exceed 5 pages.

3. RESEARCH PLAN AND ENVIRONMENT (PAGE 3.1)

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

- **A. Hypothesis and Specific Aims.** List the hypotheses, objectives, and goals of the research proposed and describe the specific aims briefly. In addition, state the anticipated impact of the research.
- **B.** Background and Significance. Concisely summarize and critically evaluate related work done by others. The critique of the literature should also include pertinent evidence that informs your approach and should address critical gaps in knowledge. Additionally, the model(s) that underpin(s) the research approach and forms the basis of your conceptual framework should be summarized here. If aims are realized, how will the results of this study impact cancer patients, clinical practice, the public's health, and/or policy?
- **C. Innovation.** Provide a rationale for why this proposed research is novel/innovative.
 - Describe how the research proposes meaningful improvements or addresses critical gaps.
 - Explain how the application challenges and seeks to shift current research or paradigms.
 - Describe any novel theoretical concepts, approaches or methodologies, to be developed or used, and any advantage over existing methodologies.
- **D. Preliminary Studies and Previous Experience.** Provide results of research accomplished by you that are relevant to this proposal; reprints or preprints may be included in the appendix. **Note:** The entire application is considered confidential, including reports of unpublished research.
- E. Research Design and Methods. 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. Include the involvement of Clinical Pipe™ in the research plan and if it's not currently installed, describe the timeline and plan for installation. 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. When available, including high level summary information about the clinical trial used will help ensure feasibility (e.g., NCT number, EDC, trial status at the center, and Schedule of Assessments (SOA)).
- **F. Environment.** Briefly describe the space and equipment available for you to carry out the proposed research project. Investigators must have an institutional commitment of research facilities. This section is of major importance for applicants whose appointment is not in the tenure stream.
- **G. References.** The list of references should correspond to the citations under headings A-E above. Each literature citation should include the names of all authors, title, book or journal, volume number, page numbers, and year of publication. There is no page limit for references.

4. DETAILED BUDGET

Complete the budget page located online at ProposalCentral. Use a start date of January 1, 2026.

A. Subcontracts. If any portion of the proposed research is to be carried out at another institution add a subcontract, enter the name of that institution, and select the years associated with the subcontract. Under each category within the detailed budget section (Personnel, Equipment, Supplies, Travel, Miscellaneous), include any budgeted items associated with the subcontract and select the subcontract from the dropdown menu on the right to tag the item. Include the subcontract(s) in the budget justification section.

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.

B. Personnel. Names and positions of all key personnel must be individually listed and the percentage of time to be devoted to the project by each person should be noted, even when salary is <u>not</u> requested. 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 collaborators should be provided in the Justification of Budget section of the application.

If the individual has not been selected, please list as "vacancy." Personnel may receive salary support up to a maximum that equals the National Cancer Institute salary cap, prorated per 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 5 percent of an individual's annual salary is requested then no more than 5 percent of that individual's annual cost for fringe benefits can be requested.

Note: The Society does not cover the costs of student tuition or fees for graduate or undergraduate students.

C. 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.
- **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).
- **General purpose equipment** Equipment such as computers or laptops used primarily or exclusively in the actual conduct of the proposed scientific project.
- **D.** Supplies. Group into major categories.
- **E. Travel.** List all travel expenses. Travel expenses should be appropriate and related to the ACS research award.

- **F. Miscellaneous Expenditures.** List specific amounts for each item; examples of expenditures allowed include publication costs, computer time and scientific software, and equipment maintenance.
- G. Indirect Costs. Indirect costs are not allowed.
- **H. Total Amount Requested.** The budget total should reflect a maximum duration of 2-years. The maximum allowable budget is \$250,000.

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.

5. JUSTIFICATION OF BUDGET

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

6. BIOGRAPHICAL SKETCHES OF KEY PERSONNEL (PAGE 4.1)

Complete the NIH Biosketch template for all Key Personnel involved in the project. Follow the formats and instructions provided by the NIH. Applicants may use the ACS template provided in ProposalCentral or the NIH template.

7. OTHER SUPPORT (PAGE 5.1)

Applicants should ensure that they include all requested items listed below, especially when modifying Other Support documents that were prepared for other funding agencies. The ACS does not require applicants and Key Personnel to sign their Other Support document.

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

- **A. Current Support.** List all current funding from intramural and extramural sources (e.g., institutional awards and grants from for-profit and not-for-profit agencies, including other grants from the American Cancer Society). Provide for each award:
 - a. Source of funds: the organization providing the support
 - b. Grant number
 - c. Project title
 - d. Inclusive dates of approved or proposed project. For example, in the case of NIH support, provide the dates of the approved or proposed competitive segment.
 - e. Total direct costs
 - f. 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). Provide for each award:

- a. Source of funds: the organization providing the support
- b. Project title
- c. Inclusive dates of approved or proposed project. For example, in the case of NIH support, provide the dates of the approved or proposed competitive segment.
- d. Total direct costs
- e. Role (e.g., PI, co-PI, co-I, etc.) and percent effort or person-months. 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 or would interfere with the PI's budgeted effort on the ACS proposal.

- **C. Institutional Support.** The following information should only be included on the Principal Investigator Other Support document:
 - 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.

The Statement of Institutional Support written by the Department Chair should align with the details provided by the PI in Section C of this template.

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

Provide a list of collaborators, co-investigators, and consultants on the template and upload the letters of support provided by each. The letter should outline the role that person will play with sufficient detail for evaluation of the value of the individual contribution. Upload the template with "Not Applicable" in the body if there are no collaborators, co-investigators, etc.

9. COMPLIANCE STATEMENTS (PAGE 7.1-7.2)

For applicants performing research that does not involve humans/is exempt, check the box that most appropriately describes your research.

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 population by race	Estimated total number of subjects
50% White	100 (200 x 0.50)
50% Black	100 (200 x 0.50)

Potential benefits and risks and knowledge gained: Succinctly describe the potential benefits and risks to subjects (physical, psychological, financial, legal, or other). Explain 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 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 from human subjects and how it will be collected, managed, and protected (e.g., demographic data elements). Specify who will have access to such 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

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.

10. STATEMENT OF INSTITUTIONAL SUPPORT (PAGE 8.1)

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

11. APPENDIX TO APPLICATION

In addition to the application templates, other key documents may be uploaded and submitted as part of the application. Applicants are urged to keep this section as brief as possible. It is not necessary to number the pages of the appendix, but please list by categories (i.e., reprints, preprints, etc.) in the Table of Contents of the application.

III. REVIEWER GUIDELINE CRITERIA

Reviewers provide feedback on the following criteria, focusing on the strengths and weaknesses of the proposal.

1. ALIGNMENT WITH THE RFA

Has the applicant identified how the proposed project accelerates cancer research by improving access, representativeness, and/or efficiency of clinical trials?

2. PROJECT OVERVIEW

Provide a brief overview of the project.

3. SIGNIFICANCE, INNOVATION, AND CANCER RELEVANCE

Does the project address an important problem or a critical need/barrier to progress in the field? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or some aspect of the cancer continuum be impacted? Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? How is this research relevant to persons at risk for or living with cancer and their family members, caregivers, friends, and community?

4. 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 a feasible plan for collaboration, where applicable?

5. APPROACH

Is the proposed research feasible and are the conceptual or clinical framework, design, methods, and analyses adequately developed, well-integrated, well-reasoned, and appropriate to the aims of the project? Is the research timeline realistic? Are potential pitfalls, alternative approaches, and future plans articulated?

6. 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, collaborative arrangements, or emerging technologies?

7. LIKELIHOOD OF SUCCESS

Degree to which the PI/research team is likely to achieve stated aims within the timeline, budget environment, and other resources available and are their findings/data actionable in some way at the end of the project period.

8. 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 percent effort of key personnel appropriate? Is there potential overlap with the Pl's other funded research? If the budget includes a request for funds to be expended outside the United States or its territories, is an explanation of why such costs are essential included and justified?

9. 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 their 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.

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.

APPENDIX A: CLASSIFICATION CATEGORIES - AREAS OF RESEARCH

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

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

Applicants are asked to select from the following codes:

1 - BIOLOGY

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

1.1 Normal Functioning

Examples of science that would fit:

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

1.2 Cancer Initiation: Alterations in Chromosomes

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

Genes and proteins involved in aberrant cell cycles

1.3 Cancer Initiation: Oncogenes and Tumor Suppressor Genes

Examples of science that would fit:

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

1.4 Cancer Progression and Metastasis

Examples of science that would fit:

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

1.5 Resources and Infrastructure

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

2.2 Endogenous Factors in the Origin and Cause of Cancer

Examples of science that would fit:

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

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

Examples of science that would fit:

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

2.4 Resources and Infrastructure Related to Etiology

- Informatics and informatics networks; for example, patient databanks
- Specimen resources (serum, tissue, etc.)
- Reagents and chemical standards
- Epidemiological resources pertaining to etiology
- Statistical methodology or biostatistical methods
- Centers, consortia, and/or networks
- Development, characterization and validation of new model systems for etiology, distribution of models to the scientific community or research into novel ways of applying model systems, including but not limited to computer-simulation systems, software development, in vitro/cell culture models, organ/tissue models or animal model systems. Guidance note: this should only be used where the focus of the award is creating a model. If it is only a tool or a methodology, code to the research instead.
- Education and training of investigators at all levels (including clinicians and other health professionals), such as participation in training workshops, conferences, advanced

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

3 - PREVENTION

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

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

Examples of science that would fit:

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

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

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

- Communicating cancer risk of diet to underserved populations, at-risk populations, and the general public
- Communication of nutritional interventions that reduce cancer risk
- Nutritional manipulation of the microbiome for cancer prevention

3.3 Chemoprevention

Examples of science that would fit:

- Chemopreventive agents and their discovery, mechanism of action, development, testing in model systems, and clinical testing
- Other (non-vaccine) preventive measures such as prophylactic surgery (e.g., mastectomy, oophorectomy, prostatectomy etc.), use of antibiotics, immune modulators/stimulators or other biological agents.
- Manipulation of the microbiome for cancer prevention (e.g. fecal transplant)

3.4 Vaccines

Examples of science that would fit:

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

3.5 Complementary and Alternative Prevention Approaches

Examples of science that would fit:

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

3.6 Resources and Infrastructure Related to Prevention

- Informatics and informatics networks; for example, patient databanks
- Specimen resources (serum, tissue, etc.)
- Epidemiological resources pertaining to prevention
- Clinical trials infrastructure
- Statistical methodology or biostatistical methods

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

4 - EARLY DETECTION, DIAGNOSIS, AND PROGNOSIS

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

4.1 Technology Development and/or Marker Discovery

Examples of science that would fit:

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

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

Examples of science that would fit:

 Development, refinement, and preliminary evaluation (e.g., animal trials, preclinical, and Phase I human trials) of identified markers or technologies such as genetic/protein biomarkers (prospective or retrospective) or imaging methods (optical probes, PET, MRI, etc.)

- Preliminary evaluation with respect to laboratory sensitivity, laboratory specificity, reproducibility, and accuracy
- Research into mechanisms assessing tumor response to therapy at a molecular or cellular level

4.3 Technology and/or Marker Testing in a Clinical Setting

Examples of science that would fit:

- 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

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

award is creating a model. If it is only a tool or a methodology, code to the research instead.

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

5 - TREATMENT

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

5.1 Localized Therapies - Discovery and Development

Examples of science that would fit:

- Discovery and development of treatments administered locally that target the organ and/or neighboring tissue directly, including but not limited to surgical interventions, cryotherapy, local/regional hyperthermia, high-intensity, focused ultrasound, radiotherapy, and brachytherapy
- Therapies with a component administered systemically but that act locally (e.g., photodynamic therapy, radioimmunotherapy, 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

- 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 therapostics,

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/personalised medicine
- Investigating the molecular mechanisms of drug resistance (including the role of cancer stem cells) and pre-clinical evaluation of therapies to circumvent resistance
- Development of methods of drug delivery
- Research into the development of systemic therapies to prevent recurrence

5.4 Systemic Therapies - Clinical Applications

- 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 neoadjuvant 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

Examples of science that would fit:

Development and testing of health service delivery methods

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

6.5 Education and Communication Research

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

Research into barriers to successful health communication

6.6 End-of-Life Care

Examples of science that would fit:

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

6.7 Research on Ethics and Confidentiality

Examples of science that would fit:

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

6.8 – Historical code [no longer used]

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

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

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