



JOIN US TO CONQUER KIDS' CANCERS

ST. BALDRICK'S FOUNDATION – AMERICAN CANCER SOCIETY
CHILDHOOD CANCER RESEARCH RFA: PILOT ACCELERATOR AWARD
APPLICATION INSTRUCTIONS

ELECTRONIC APPLICATION DEADLINE: April 3, 2023

AMERICAN CANCER SOCIETY, INC.
Extramural Discovery Science Department

Web site: <http://www.cancer.org>
Program Contact: kimberly.clarke@cancer.org

MISSION

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

The St. Baldrick's Foundation (SBF) mission is to support the most promising research to find cures for childhood cancers and give survivors long and healthy lives.

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I. GENERAL INFORMATION

1. ACS GRANT APPLICATION SYSTEM

- Access the ACS Research site at www.cancer.org.
- Select “Our Research” > “Apply for Grant” > “Grant Types”.
- Select link to your grant, which opens the electronic application process at proposalCENTRAL.
- Follow instructions for login/register, completion, and submission.
- Key steps:
 - 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 pcsupport@altum.com or 1-800-875-2562.

Note: Grants will be funded by both organizations, but the ACS will administer the grant and coordinate the application and peer review processes.

2. APPLICATION FORMAT

- Insert the Principal Investigator’s (PI) name in the header for each template of the application. Do not change the template footers.
- 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:** \geq 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 via email to Kimberly Clarke, PhD (kimberly.clarke@cancer.org), Director of Research Special Programs and Projects.

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

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

Change of Institution: If you change institutions between application submission and peer review, contact to inquire how this may impact the review. Update your information in proposalCENTRAL.

4. REQUIRED INFORMATION

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 for key personnel.

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).

Clinical Trial PI leads (or led) the clinical trial that is partnering with the scientific team of this project.

The table below shows which documents are required for each personnel class. See grant mechanism-specific instructions for more details.

REQUIRED SUPPORTING DOCUMENTS FOR NAMED PERSONNEL

Personnel	Designated "Key"	Biosketch	"Other support" Documentation	Included in Budget & Justification	Letters
Principal Investigator	Yes ^a	Yes	Yes	Yes	N/A
Co-Investigator	Yes	Yes	Yes ^b	Yes ^c	Letter of

					Agreement/Support ^b
Collaborator	Yes	Yes	Yes ^b	Yes ^c	Letter of Agreement/Support ^b
	No	No	No	No	
Consultant	Yes	Yes	Yes ^b	Yes ^c	Letter of Agreement/Support ^b
	No	No	No	No	
Other	No	No	No	Yes	No
Clinical Trial PI ^d	Yes	Yes	Yes	Yes	See Template 9.1

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

^b Exception: Support documentation and letters are not required for postdoctoral fellows, technicians, and graduate students.

^c If Key Personnel are not being paid (i.e., in kind), 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. If compensation is being provided elsewhere, this should be described in the Budget Justification.

^d If the Clinical Trial PI is the applicant or another member of the team then follow the required documentation for that role. Template 9.1 (Letter from Clinical Trial PI) is required in all instances.

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

Justification of Eligibility: Applicants must satisfy all eligibility requirements defined for each application type. 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. If you have a letter from the ACS Eligibility Committee, include in the Appendix and indicate this in the Table of Contents.

Justification of Designation “Priority Focus in Health Equity Research”: N/A for this RFA

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 take place at a university. The TTO will be responsible for annually 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.

ORCID Identifier (required): 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.

Committee Code: N/A for this RFA

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**. 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:

- 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 committee as well as to several general audiences, including donors. **Avoid the use of technical jargon.** This form is limited to 1500 characters, including spaces, and will truncate at that point.

Describe how the cancer screening and early detection related project contributes short- and/or 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. 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%. Descriptions of the research priorities can be found in the Screening Priority Area RFA Policies document with further details on cancer.org.

9. JUSTIFICATION OF PROJECT ALIGNMENT TO ACS RESEARCH PRIORITIES

Explain how your proposed project aligns to the selected research priority/priorities. This form is limited to 1500 characters, including spaces, and will truncate at that point. See [here on cancer.org](https://www.cancer.org) for a listing, descriptions, and specific examples of research that may fall under the ACS priority areas. If your project aligns to multiple priority areas (not a requirement), provide additional justification of the alignment to those areas in this section as well. Please make sure that the priority area or areas are clearly stated.

Organize this justification into the following sections:

- ACS Priority Alignment
- Priority Area(s) and Percent Breakdown (for example: Treatment 50%; Etiology 50%)
- Alignment with RFA Goals

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 C 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.

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 “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 and identify areas that need improvement.

Note: The ACS *requires* that all *grantees* provide their demographic data at the time of grant activation. If an applicant selects “prefer not to disclose” at the time of application, they will be required to provide the information if the grant is funded.

13. APPLICATION SUBMISSION AND REQUIRED SIGNATURES

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.

II. 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.*

1. 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.

2. BIOGRAPHICAL SKETCH OF APPLICANT (PAGE 2.1)

Complete the NIH Biosketch template. Follow the formats and instructions provided by the NIH.

3. RESEARCH PLAN AND ENVIRONMENT (PAGE 3.1)

Section A below should not exceed 1 page. Sections B-E below must not exceed 5 pages. This page limit does not include Sections F-I.

Proposals should be realistic in terms of work to be accomplished for the project proposed for funding. Failure to conform to the guidelines on type size, page length, or project scope may result in the application being returned to the investigator without review.

A. Hypothesis and Specific Aims (1 page)

List the hypotheses, objectives, and goals of the research proposed and describe the associated clinical trial and specific aims briefly. In addition, state the anticipated impact of the research having high potential for rapid clinical benefit for children with cancer.

B. Background and Significance

Concisely summarize and critically evaluate related work done by others. Specifically state how the successful completion of the proposed work will advance scientific knowledge or aspects of clinical practice to provide new knowledge regarding mechanisms for novel agents or combinations regimens, treatment resistance, novel biomarkers, toxicity, and insights for precision medicine approaches.

The critique of the literature should also include:

- Pertinent evidence-based interventions that inform your approach
- Critical gaps in knowledge
- The model(s) that underpins the research approach and that forms the basis of your conceptual framework.
- What will be the impact of this study on childhood cancer?

C. Innovation

Explain how the application challenges and seeks to shift current research understanding or clinical practice paradigms. Describe how the research proposes meaningful improvements or addresses critical gaps. Describe any novel theoretical concepts, approaches or methodologies, instrumentation or intervention(s) to be developed or used. Explain any refinements, improvements, or new applications of theoretical concepts, approaches or methodologies, instrumentation or interventions.

D. Preliminary Studies and Previous Experience

Preliminary data is not required. However, if you have preliminary data, provide the results of your research that are relevant to this proposal in a sufficiently comprehensive manner to indicate their significance. Reprints or preprints may serve in lieu of a detailed report and should 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. 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. Plans for the Team and Dissemination of Project Findings (3 pages max)

Use this section for a concise summary of how the team will function, metrics of progress, and what will be actionable from the research-translation to practice and future research plans. **The following details should also be included:**

- **Leadership Plans:** Describe how the team will function in an integrated way to achieve their specific aims including team roles and responsibilities; decision making and problem-solving processes; monitoring and reporting progress; meeting mode and frequency; and communication strategy for planning and dissemination.

- **Project Timeline:** Include a timeline with milestones for the project period.
- **Potential for Knowledge Transfer:** Clearly define your plan about how the results of the study will be used to develop future research and the study's practical clinical benefit.

G. 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. The amount of committed space must be verified by the Department Chair. This section is of major importance for applicants whose appointment is not in the tenure stream.

H. Statement of Science Outreach and Advocacy (1 page max)

The ACS considers it important that scientists communicate the results of their research to a wide range of communities. Explain the potential impact of your proposed project on your community and to the American Cancer Society's mission of eliminating cancer as a major health problem.

Share any previous experiences in science outreach and advocacy. Describe the plan for disseminating the team's work in the cancer arena through advocacy, awareness, education, or service. Also include your plans for sharing your research with your (non-academic) community members and for engaging with community partners in the dissemination process.

I. References

The list of references should correspond to the citations under headings a-d above. Each literature citation should include the names of all authors, title, book or journal, volume number, page numbers, and year of publication. There is no page limit for the list of references.

4. DETAILED BUDGET

Pilot Accelerator Awards may not exceed \$100,000 per year of direct costs plus 20% indirect cost. The total maximum allowable budget is \$240,000 for two years. **The grant term starts January 1, 2024.**

A. Personnel

List each name and position of all key personnel and the percentage of time they need to devote to the project, even when salary is not requested (in-kind). **The PI must list at least 10% time and effort to the proposed research.**

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 10 percent of an individual's annual salary is requested,

then no more than 10 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 1 year. List separately and justify the need for each item of permanent equipment. **Note:** The cost of permanent equipment **is not included** in the Direct Cost total used to calculate Indirect Costs.
- **Small or expendable equipment:** Defined as expendable property with a purchase cost per unit that is less than \$5,000 and/or that has a short service life (<1 year). **Note:** The cost of small or expendable equipment **may be included** in the Direct Cost total used to calculate Indirect Costs.
- **General purpose equipment:** Equipment such as computers or laptops used primarily or exclusively in the actual conduct of the proposed scientific project are considered direct cost and may be included in the Direct Cost total used to calculate Indirect Costs. Computers, laptops, or other general-purpose equipment that will be used on multiple projects or for personal use should not be listed as a direct cost and should not be included in the calculation for indirect cost.

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

D. Travel. Travel funds are restricted for domestic travel within the US, its territories, and Canada.

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

F. Subcontracts

If any portion of the proposed research is to be carried out at another institution, enter the total direct costs (enter indirects claimed by the secondary institution in the indirect cost category) on the online budget detail page on proposalCENTRAL. Then provide a categorical breakdown of costs using the Subcontractor Budget and Justification form, using one form per subcontractor. Upload the form(s) when complete, entering the subcontractor's name in the "describe attachment" field.

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

Note: Use of any subcontractor outside the US **must be approved in writing** by ACS before any grant-funded work is done.

- **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, an indirect cost allowance of up to 20% of the direct costs is permitted, excluding permanent equipment.

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

Indirect costs should be itemized for the primary institution and any subcontracting institutions (if subcontracts are in the budget).

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 inclusive of direct and indirect costs. Enter the total amount requested for the project period on the Title Page of the application. The amount entered on the title page must match the total costs in the 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.

5. JUSTIFICATION OF BUDGET

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

Provide details of contractual arrangements with Key Personnel in this section.

6. BIOGRAPHICAL INFORMATION OF KEY PERSONNEL (PAGE 4.1)

Complete the NIH Biosketch template. **Note:** Follow the formats and instructions provided by the NIH.

7. OTHER SUPPORT (PAGE 5.1)

The PI must verify that the funds in this application will cover correlative or additional work, not work already funded through the trial or other grants.

Projects supported all or in part by another agency are not allowed for submission; this means that projects are considered to overlap if there are **any** shared *Specific Aims or areas of budgetary overlap*. The ACS Scientific Director will make the final decision regarding any questions of overlap. The ACS/SBF does not negotiate partial funding of grants with overlapping specific aims.

The only exceptions are:

- Funds provided by the institution as “start-up” support to develop a new laboratory or to gather pilot data.

- Awards that provide only pilot salary support for the PI, unless it is covered by the other agency, no additional salary support for the PI may be requested in this grant application.

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

A. Current Support: List all current awards including funding from intramural and extramural sources (e.g., institutional awards, and grants from for-profit, and not-for-profit agencies, including other grants from the ACS or SBF). For **each** award provide:

- Source of funds
- Grant number
- Title of project
- Inclusive dates of approved or proposed project. For example, in the case of NIH support, provide the dates of the approved/proposed competitive segment.
- Total Costs
- Percent Effort/Person Months: For an active project, provide the level of actual effort in person months (even if unsalaried) for the current budget period. Classify person months as academic, calendar, and/or summer.
- Outline the goals of the project in a brief paragraph
- 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 or SBF). For **each** award provide:

- Source of funds
- Grant number
- Title of project
- Inclusive dates of approved or proposed project. For example, in the case of NIH support, provide the dates of the approved/proposed competitive segment.
- Total Costs
- Percent Effort/Person Months: For an active project, provide the level of actual effort in person months (even if unsalaried) for the current budget period. Classify person months as academic, calendar, and/or summer.
- Outline the goals of the project in a brief paragraph
- A clear indication of overlap and differences between this grant and the proposed study. If necessary, include an explanatory letter in the Appendix.

C. Institutional Support (required for the PI only):

- For early-stage investigators, 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.
- The current term of the applicant's appointment.

Applicants, who are non-tenure track faculty, 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.

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

Provide a list of collaborators/consultants and upload the letter from each of them as an attachment. The letter should outline the role that person will play with enough detail for evaluation of the value of that person’s contribution. You are not required to use the template.

However, **for the Letter of Collaboration from the Clinical Trial PI**, please utilize the Clinical Trial PI Letter of Collaboration Template to ensure that all required information is presented in the letter (see PAGE 9.1).

9. COMPLIANCE STATEMENTS (PAGE 7.1)

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 population by race	Estimated total number of 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.

Note: Funds may not be used for human embryonic stem cell 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.

*For additional protections for vulnerable populations, see <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 Post Award Management 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.

Resource Sharing Plan

Researchers should transparently report on what they have done to authenticate key resources so that consensus can emerge. It is essential that Investigators share renewable reagents and data developed with funds or used in the funded project with other qualified investigators. Investigators are expected to encourage and facilitate such sharing. Proposals may include only one combined Renewable Reagent and Data Sharing Plan.

- What is your plan for sharing the data and reagents (e.g., mouse models and other key reagents that are not commercially available, genomics, consumables, etc.; 600 characters max)?
- What will be your policies for access and sharing the data during the life of your award and after award closeout (5000 characters max)?
- What will be the format, mode of delivery and timetable for data distribution (5000 characters max)?
- Please include any provisions for appropriate protection of privacy, confidentiality, security or intellectual property (5000 characters max).

10. STATEMENT OF INSTITUTIONAL SUPPORT (PAGE 8.1)

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

11. LETTER OF COLLABORATION FROM CLINICAL TRIAL PI (PAGE 9.1)

A letter of collaboration from the approved clinical trial PI is required. This letter should include the following information:

- Approved clinical trial name, sponsor, Clinical Trials.gov identifier number (if available) and project period.
- Acknowledgment of approval for this applicant to partner with your trial.
- Verification that the funds in this application will cover correlative or additional work, not work already funded through the trial.
- Briefly summarize what permissions, resources, activities, etc. you agree to extend to this applicant to conduct their proposed research.
- How do you perceive this research will accelerate progress in childhood cancer?
- Any other pertinent information

12. APPENDIX TO APPLICATION

You may upload and submit other key documents as part of your application. However, applicants are urged to keep this section as brief as possible.

Appended materials may include:

- Letters of support
- 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 (i.e., reprints, preprints, etc.) in the Table of Contents of the application.

III. REVIEWER GUIDELINE CRITERIA

For each section, reviewers will focus on the strengths and weaknesses. The final score should align with the written critique.

1. ALIGNMENT WITH ACS RESEARCH PRIORITY AREAS AND PRIORITY AREA RFA GOALS

Has the team identified and appropriately justified how their project fits within one or more ACS research priority areas? Have they appropriately justified how their project aligns with the goals of the Priority Area RFA to facilitate more widespread cancer screening and early detection culminating in reduced cancer mortality?

2. RESEARCH PLAN

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

3. 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? Will it provide new knowledge regarding mechanisms for novel agents or combination regimens, treatment resistance, novel biomarkers, toxicity, or insights for precision medicine approaches? How is the research relevant to improving quality of life and optimizing care for children with cancer?

4. RESEARCH PLAN – INNOVATION/IMPROVEMENT

What is the potential that the proposed team science 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? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

5. RESEARCH PLAN – LEAD PI/RESEARCH TEAM

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

6. RESEARCH PLAN – APPROACH

Are the study design, conceptual or clinical framework, methods for implementation, data collection and analysis adequately developed and appropriate for answering the research question(s)? Where appropriate, are proposed recruitment and/or case ascertainment methods well developed? If applicable, is there a plan for recruiting under-represented subjects? Is the sample size adequate? Is the research timeline realistic? Are potential pitfalls, alternative approaches, and future plans articulated? Do the investigators include relevant limitations?

7. 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 the institutional support, equipment, and other physical resources available to the investigators adequate for the project proposed? A letter from the collaborating clinical trial PI is required.

A letter of collaboration from an approved clinical trial PI is required (**Application Page 9.1**). This letter should include the following information:

- Approved clinical trial name, sponsor, Clinical Trials.gov identifier number (if available) and project period.
- Acknowledgment of approval for this applicant to partner with your trial.
- Verification that the funds in this application will cover correlative or additional work, not work already funded through the trial.
- Briefly summarize what permissions, resources, activities, etc. you agree to extend to this applicant to conduct their proposed research.
- How do you perceive this research will accelerate progress in childhood cancer?
- Any other pertinent information

8. STATEMENT OF SCIENCE OUTREACH AND ADVOCACY

FEEDBACK OPTIONAL, THIS SECTION SHOULD NOT BE CONSIDERED IN 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?

9. LIKELIHOOD OF SUCCESS AND FUTURE FUNDING

Is it likely that the PI/Research Team will achieve the proposed aims within the timeline, budget, environment, and other resources available for rapid clinical benefit? A clearly defined plan regarding future use of study findings to pursue subsequent funding is an integral part of this mechanism. Is there a clearly defined plan regarding how the data and/or process information generated will be used to develop a project?

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. Are the budget items justified, specified, and accurate? Is the percent effort of key personnel appropriate? Is there potential overlap with other funded research? If the budget includes a request for funds to be expended outside the United States or its territories, is there 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.

11. COMPLIANCE STATEMENTS

NOT TO BE CONSIDERED IN SCORING

1. **Human Subjects:** If applicable, evaluate the plans for protection of human subjects from research risks justified in terms of the scientific goals and research strategy proposed. For

example, are the potential benefits and risks to subjects articulated reasonable and appropriate given the study design? Are the plans for conducting sub-analysis by group, data security and confidentiality, biohazards and data and safety monitoring adequate?

2. **Inclusion of Women, Minorities, and Children:** When the proposed project involves human subjects, evaluate the adequacy of the proposed plans for inclusion or exclusion of minorities, male and female genders, as well as children.
3. **Vertebrate Animals:** Evaluate the plan for live, vertebrate animals as part of the scientific assessment according to the following points: 1) necessity for the use of the animals and species proposed; 2) appropriateness of the strains, ages, and gender; 3) justifications for, and appropriateness of, the numbers of animals.
4. **Biohazards:** Assess whether materials or procedures proposed are potentially hazardous to research personnel and/or the environment, and if needed, determine whether adequate protection is proposed.

APPENDIX A: CLASSIFICATION CATEGORIES - AREAS OF RESEARCH

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

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

Applicants are asked to select from the following codes:

1 – BIOLOGY

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

1.1 Normal Functioning

Examples of science that would fit:

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

1.2 Cancer Initiation: Alterations in Chromosomes

Examples of science that would fit:

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

1.3 Cancer Initiation: Oncogenes and Tumor Suppressor Genes

Examples of science that would fit:

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

1.4 Cancer Progression and Metastasis

Examples of science that would fit:

- Latency, promotion, and regression

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

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 a preventive measure.

3.6 Resources and Infrastructure Related to Prevention

Examples of science that would fit:

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

4 – EARLY DETECTION, DIAGNOSIS, AND PROGNOSIS

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

4.1 Technology Development and/or Marker Discovery

Examples of science that would fit:

- Discovery or identification and characterization of markers (e.g., proteins, genes, epigenetic), and/or technologies (such as fluorescence, nanotechnology, etc.) that are potential candidates for use in cancer detection, staging, diagnosis, and/or prognosis
- Use of proteomics, genomics, expression assays, or other technologies in the discovery or identification of markers

- Defining molecular signatures of cancer cells, including cancer stem cells (e.g., for the purposes of diagnosis/prognosis and to enable treatment decision planning in personalized/stratified/precision medicine)

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

Examples of science that would fit:

- Development, refinement, and preliminary evaluation (e.g., animal trials, preclinical, and Phase I human trials) of identified markers or technologies such as genetic/protein biomarkers (prospective or retrospective) or imaging methods (optical probes, PET, MRI, etc.)
- Preliminary evaluation with respect to laboratory sensitivity, laboratory specificity, reproducibility, and accuracy
- 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

Examples of science that would fit:

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

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

5 – TREATMENT

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

5.1 Localized Therapies - Discovery and Development

Examples of science that would fit:

- Discovery and development of treatments administered locally that target the organ and/or neighboring tissue directly, including but not limited to surgical interventions, cryotherapy, local/regional hyperthermia, high-intensity, focused ultrasound, radiotherapy, and brachytherapy
- Therapies with a component administered systemically but that act locally (e.g., photodynamic therapy, radioimmunotherapy, 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/personalised medicine
- Investigating the molecular mechanisms of drug resistance (including the role of cancer stem cells) and pre-clinical evaluation of therapies to circumvent resistance
- Development of methods of drug delivery
- Research into the development of systemic therapies to prevent recurrence

5.4 Systemic Therapies - Clinical Applications

Examples of science that would fit:

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

Examples of science that would fit:

- Informatics and informatics networks; for example, clinical trials networks and databanks

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

6 - CANCER CONTROL, SURVIVORSHIP, AND OUTCOMES RESEARCH

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

6.1 Patient Care and Survivorship Issues

Examples of science that would fit:

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

that lessen treatment-related morbidity and promote psychological adjustment to the diagnosis of cancer and to treatment effects

- Burdens of cancer on family members/caregivers and interventions to assist family members/caregivers
- Educational interventions to promote self-care and symptom management
- Research into peer support, self-help, and other support groups
- Behavioral factors in treatment compliance

6.2 Surveillance

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

Examples of science that would fit:

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

6.6 End-of-Life Care

Examples of science that would fit:

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

6.7 Research on Ethics and Confidentiality

Examples of science that would fit:

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

6.8 – Historical code [no longer used]

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

Examples of science that would fit:

- Informatics and informatics networks

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