



**YOSEMITE-AMERICAN CANCER SOCIETY AWARD**  
**Instructions for Submitting an Application**

**Effective March 2026**

**ELECTRONIC APPLICATION DEADLINE: June 24, 2026**

**All Inquiries: [Yosemite@cancer.org](mailto:Yosemite@cancer.org)**

**YOSEMITE-AMERICAN CANCER SOCIETY AWARD  
APPLICATION INSTRUCTIONS**

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## I. GENERAL GUIDANCE AND PROPOSALCENTRAL SECTIONS

### 1. GENERAL INFORMATION FOR APPLICANTS

- This instructions document provides guidance for the preparation of applications to be funded under the Yosemite-American Cancer Society request for applications.
- It is *strongly recommended* that applicants review the eligibility requirements in the grant policies to ensure they are eligible prior to applying. Applications may be withdrawn if an applicant or institution do not meet the eligibility criteria.
- **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 Grant Policies.

### 2. GRANT APPLICATION SYSTEM

- We utilize [ProposalCentral](#) for the preparation, submission, review, and management of all grant applications and awards. Follow instructions for login/register, completion, and submission.
- Key steps:
  - Filter on the “Grant Opportunities” Tab > Choose “American Cancer Society” > Review available grant programs > Find grant program of interest > Select “Apply Now” to access grant application materials.
  - After selecting the grant mechanism for which you intend to apply, enter Project Title (unless already displayed) > SAVE. This permits access to all other application components.
  - Saved applications are stored under the “Proposals” tab in the applicant’s ProposalCentral account.
- See ProposalCentral login page for tutorials and additional details about the grant application process.
- For assistance with issues associated with ProposalCentral, click “Help” or contact ALTUM Customer Service at [pcsupport@altum.com](mailto:pcsupport@altum.com) or 1-800-875-2562.

### 3. UPDATES OF INFORMATION

The following updates should be communicated as soon as possible.

**Withdrawal of Application:** Notify [yosemite@cancer.org](mailto:yosemite@cancer.org) promptly of your intent to withdraw your application. Include in your letter or email, the PI name, application number, and reason for withdrawal. If the project has been funded by another organization, please list that funding agency.

**Change of Address:** Notify [yosemite@cancer.org](mailto:yosemite@cancer.org) if a mailing address, email address, or phone number has changed since submission. Include the PI name and application number on the correspondence and update your information in ProposalCentral.

**Change of Institution:** If you change institutions between application submission and peer review, contact [yosemite@cancer.org](mailto:yosemite@cancer.org) to inquire how this may impact the review.

### 4. TITLE PAGE, APPLICANT, AND INSTITUTION 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 PDF formatted title page.

**Proposal Type:** Using the dropdown menu, select new, resubmission, or renewal (if applicable for your grant mechanism).

**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.

- **Citizenship Status (mandatory):** On ProposalCentral under “Professional Profile”, indicate your current citizenship status and country of citizenship.
- **Degree and Independent Position Dates:** Under Professional Profile, indicate the date (months and year) your terminal degree was awarded and when your first independent faculty position (or equivalent) began, if applicable.
- **Permanent Email:** We require applicants to provide a permanent email address, such as a personal email address, that is not affiliated with your work. ACS requests this information so we have a consistent, long-term way to contact grantees for impact tracking and communication purposes.
- **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.

- **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 for submission. The PI must give the Institutional Official access to the application for e-signing to be completed. Provide a mailing address for disbursement of funds, in the event that your grant is awarded funding.
- **Technology Transfer Officer (TTO):** Indicate the name and email address of the TTO. The TTO is responsible for technology transfer and other aspects of the commercialization of research that takes place at a university. The TTO will be responsible for reporting all IP updates 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.

## 5. KEY PERSONNEL

Add personnel associated with the application and included in the budget and justification by entering their email address. Select the role that corresponds most closely with the person’s contribution to the project (see definitions below).

**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). **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 required to designate >0% effort, even if they are not being compensated.

## **Key Personnel Roles and Definitions**

The **Principal Investigator** assumes the authority and responsibility to direct the project. Multiple Principal Investigators are not permitted for this award.

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).

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

### **REQUIRED SUPPORTING DOCUMENTS FOR NAMED PERSONNEL**

<b>Personnel</b>	<b>Designated “Key”</b>	<b>Biosketch</b>	<b>“Other Support” Documentation</b>	<b>Included in Budget &amp; Justification</b>	<b>Letters</b>
Principal Investigator	Yes <sup>a</sup>	Yes	Yes	Yes	N/A
Co-Investigator	Yes	Yes	No	Yes <sup>c</sup>	Letter of Agreement/Support <sup>b</sup>
Collaborator	Yes	Yes	No	Yes <sup>c</sup>	Letter of Agreement/Support <sup>b</sup>
	No	No	No	No	
Consultant	Yes	Yes	No	Yes, if paid <sup>c</sup>	Letter of Agreement/Support <sup>b</sup>
	No	No	No	Yes, if paid	
Other	No	No	No	Yes	No

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

<sup>b</sup> For postdoctoral fellows, technicians, and graduate students, supporting documents are not required.

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

## **6. GENERAL AUDIENCE SUMMARY**

Complete this in the designated textbox in ProposalCentral, under “General and Technical Abstract and Project Coding.” This form is limited to 3,100 characters including spaces and will truncate at that point. If symbols or Greek characters must be used, they should be spelled out to avoid formatting problems. Comply with the character limit to permit readers (including peer reviewers) to fully appreciate the “big-picture perspective” of the proposal.

The general audience summary provides an overview of the proposed research for people who are **not** trained in the sciences. Describe concisely the background, significance, question(s) being asked, information to be obtained, and potential impact of your proposed research. This summary may be read by community research partners, ACS and Yosemite 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 audience summary to evaluate how the proposed work will benefit cancer patients and their families and is considered when scoring the application.
- Staff may use the summary for communicating with external people about funded projects. 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. Because Community Research Partners utilize this summary when evaluating and scoring applications, applicants should clearly articulate the value and potential impact of the proposed research. *See examples of General Audience Summaries in Appendix A.*

## 7. STRUCTURED TECHNICAL ABSTRACT

Complete this in the designated textbox in ProposalCentral, under “General and Technical Abstract and Project Coding.” The structured technical abstract is a summary of the proposed research or scholarly project for **general scientific** audiences. *See examples of Structured Technical Abstracts in Appendix B.*

Organize the abstract into the following sections:

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

This form is limited to 3,100 characters including spaces and will truncate at that point. Comply with the character limit to permit peer reviewers to fully appreciate the technical synopsis. Do not include proprietary information.

## 8. STATEMENT OF CANCER RELEVANCE AND IMPACT

Complete this in the designated textbox in ProposalCentral, under “General and Technical Abstract and Project Coding.” This section should be written for a lay audience. Avoid the use of technical jargon. This form is limited to 1,500 characters including spaces and will truncate at that point.

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

## 9. PROJECT CODING: CSO CODES AND CANCER TYPES

Complete this in the designated textbox in ProposalCentral, under “General and Technical Abstract and Project Coding.” **Note: Project coding is not considered at peer review. Red asterisks in ProposalCentral indicate required fields.**

Your selection of project codes 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.

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

## 10. 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 an approved grant can be activated. Enter the date of the most recent IACUC approval in the space provided.

All research supported by this award (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 granting institutions 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. Failure to comply may result in withholding of payments and/or cancellation of funding. In addition, certification of the approval, clearly labeled with the assigned application number, must be uploaded to ProposalCentral within 3 months of grant activation.

If a grant is funded, it is the responsibility of the institution to immediately report 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.

## 11. PI DATA SHEET

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

## 12. RESUBMISSION

**All resubmissions must create a new application in ProposalCentral.**

**Resubmission guidelines:**

- Submit a complete application electronically in ProposalCentral.
- The title of the project can be altered but the application **must** be marked as a resubmission.
- Select the appropriate application number from the list of your prior submissions in ProposalCentral.

- Resubmitted applications to the **2026 Yosemite-American Cancer Society RFA** must align with the **current scientific scope** as described in the Policies and the RFA announcement. If the research plan changes by approximately 50% or more since the initial 2024 submission, the application should be submitted as a new application.

### 13. APPLICATION TEMPLATE FORMAT GUIDELINES

- Insert Principal Investigator (PI) name in the header for each template of the application. Do not change the footers on the templates.
- Application documents may be single- or double-spaced (if single spacing, enter a space between paragraphs).
- **Type size:** 12-point Times New Roman or 11-point Arial are the minimum font sizes for the text; 10-point Times New Roman or 9-point Arial font type may be used for figures, legends, and tables.
- **Margins:**  $\geq 0.5$  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, Budget & Justification, or the Appendices.
- **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.

### 14. 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 the specified deadline date. If the standard deadline falls on a weekend or holiday, applications will be due 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. PREPARING THE APPLICATION

### 1. COVER PAGES

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

On the title page, select the topic area that aligns with your proposal (see the Policies or RFA announcement for more information). Projects must align with one of the following topic areas:

- Topic 1: Regulatory mechanisms
- Topic 2: Protein modulation

### 2. APPLICATION TEMPLATES

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

See [application format guidelines](#) for additional information on template formatting.

### 3. TABLE OF CONTENTS (PAGE 1.1)

The Table of Contents is pre-numbered, corresponding to the page numbers for the first page of each application section. Complete the Table of Contents by indicating the appropriate page numbers for the Research Plan section; the Table of Contents should not exceed 2 pages.

Itemize any appendices in order of appearance at the bottom of the Table of Contents template; appendices do not need to have page numbers.

### 4. BIOGRAPHICAL SKETCH OF APPLICANT (PAGE 2.1)

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

**Note:** If the NIH has modified the NIH Biosketch, applicants may use the newly modified template, or the template provided in ProposalCentral.

### 5. REPLY TO PREVIOUS REVIEWS (PAGE 3.1)

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

**All resubmissions must create a new application on ProposalCentral.**

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

### 6. PREVIOUS CRITIQUES (resubmissions only)

All resubmissions must include a copy of the previous critiques. Electronic copies of the critiques for your previous submission(s) can be downloaded from your "Submitted" page on ProposalCentral. Select the link to "View Review Info," then click "Print" to save it as a .pdf. Upload the document to your new application with the other proposal sections.

## 7. RESEARCH PLAN AND ENVIRONMENT (PAGE 4.1)

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

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

- A. Specific Aims** (*not to exceed 1 page*). Provide an overview of your proposed project, and where appropriate, list the hypotheses, objectives, and goals of your proposed research and briefly describe the scientific aims.
- B. Background and Significance.** Concisely summarize and critically evaluate relevant work done by your research team and others. Specifically state how the successful completion of the work proposed will advance scientific knowledge that is relevant to cancer discovery, prevention, treatment, survivorship, and/or healthcare delivery.
- C. Innovation.** Explain how the application fills an unmet gap in the field and/or challenges and seeks to shift current research or clinical-practice paradigms. Describe novel, refined, and/or new applications of theoretical concepts, approaches, methodologies, technologies, or interventions to be developed or used, and the advantage they offer over existing ones.
- D. Preliminary Studies.** While preliminary data are not required for this grant mechanism, there should be sufficient evidence to support funding a novel discovery or new significant research direction in cancer. You may therefore choose to provide results of your prior research that are relevant to this proposal. Reprints or preprints may be included in the Appendix. Note that the entire application is considered confidential.
- E. Research Design.** Describe your overall hypotheses, proposed methods, procedures, and data analysis plan in sufficient detail to permit evaluation by other scientists; include your rationale for approaches and analysis. Explain your project’s feasibility and how the experiments proposed will address the Specific Aims. Discuss potential difficulties and limitations of your proposed methods and provide alternative approaches. Inclusion of an experimental timeline can be helpful.
- F. Experimental Details** (*optional – not to exceed 3 pages*). This section should only be used if more in-depth description of the experimental design, technologies, or assays are needed to convey the specific approaches and procedures proposed. This section is also appropriate for articulating specifics regarding how you plan to apply findings from this research.
- G. Environment.** Briefly describe the space, resources, and equipment available to carry out the proposed research (e.g., space designated specifically for your research program, shared space and/or core facilities), and include details of how this environment will support your research. Investigators must have an institutional commitment of research facilities, and the amount of committed space must be verified (see Statement of Institutional Support below).
- H. References.** Each literature citation should include title, authors, book or journal, volume number, page numbers, and year of publication. There is no page limitation; this section is not included in the 5-page limit of Sections (B) through (E).

## 8. DETAILED BUDGET

Complete the budget page located online at ProposalCentral. Use a start date of January 1, 2027. Please review the Yosemite-ACS grant policies (Expenditures, page 10) for a list of items that may not be claimed as a direct cost.

**A. Personnel.** Names and positions of all key personnel must be individually listed, and the percentage of time to be devoted to the project by each person should be entered. List all key personnel (defined as individuals who will participate actively in the design and/or execution of the studies and have a level of effort >0%), and any non-key personnel who will be compensated for their effort (e.g., graduate students). Details of contractual arrangements with personnel should be provided in the Justification of Budget section.

If the individual has not been selected, please list as "vacancy." If a Key Person is not receiving salary, you can request \$0 for salary, but their percent effort is still required. Their effort and contribution to the project should be outlined in the Budget Justification even if they are not being compensated.

The costs to the institution of employee fringe benefits should be indicated as a percent of the employee's salary. The amount of fringe benefits requested must be prorated to the salary requested. For example, if 50 percent of an individual's annual salary is requested, then no more than 50 percent of that individual's annual cost for fringe benefits can be requested.

**NOTE:**

- See above for definitions of [key personnel](#).
- Do not include the costs of student tuition or fees for graduate or undergraduate students.

**B. Equipment**

- **Permanent equipment.** Defined as items of nonexpendable property with a purchase cost per unit that equals or exceeds \$5,000 with a useful life of more than one year. List separately and justify the need for each item of permanent equipment. Note: the cost of permanent equipment is not included in the direct cost total used to calculate indirect costs.
- **Small or expendable equipment.** Defined as expendable property with a purchase cost per unit that is less than \$5,000 and/or that has a short service life (<1 year). Note: Equipment that equals or exceeds \$5,000 with a useful life of more than one year is not included in the direct cost total used to calculate indirect costs.
- **General purpose equipment.** Equipment such as computers used primarily or exclusively in the actual conduct of the proposed scientific project are considered direct costs and may be included in the direct cost total used to calculate indirect costs. Computers or other general-purpose equipment that will be used on multiple projects or for personal use are not allowable expenditures.

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

**D. Travel.** List all travel expenses. Travel expenses should be appropriate and related to the Yosemite-American Cancer Society research award.

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

**F. Subcontracts.** If any portion of the proposed research is to be carried out at another institution, enter the total direct costs on the online budget detail page on ProposalCentral. Each subcontract should be listed separately. Then provide a categorical breakdown of costs using the Subcontractor Budget and Justification form, using one form per subcontractor. Upload the form(s) when complete, entering the subcontractor's name in the "describe attachment" field.

Subcontracts for the research project may be with public or private institutions, regardless of whether they are among the eligible institutions for this award.

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

**G. Indirect Costs.** To help the institution provide proper laboratory and clinical facilities, indirect costs of up to 10% of the direct costs are allowed, excluding permanent equipment. **No indirect costs may be applied to subcontracts.**

**H. Total Amount Requested.** Budget totals should reflect a maximum duration of 2 years and a maximum of \$300,000 direct costs plus up to \$30,000 indirect costs for a total maximum award amount of \$330,000. The amount on the application Title Page should match the total costs in the detailed budget section.

**Notes:** Applicants should not budget above or below the allowable indirect cost rate. For budgets that do not request the maximum allowable amount, if the grant is funded, we will round the total to the nearest thousand dollars. We encourage applicants to request a budget amount that is rounded to an even thousand dollars.

## 9. JUSTIFICATION OF BUDGET

Provide budget justification in the Detailed Budget section on ProposalCentral. A budget justification text box is provided for each year of funding. Justify all items of permanent equipment costing over \$5,000 as well as needs for personnel, supplies, travel, and other miscellaneous items.

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

## 10. BIOGRAPHICAL INFORMATION OF KEY PERSONNEL (PAGE 5.1)

Complete the NIH Biosketch template for all key personnel involved in the project following the formats and instructions provided by the NIH. The Biographical Sketch **may not exceed 5 pages**. All key personnel biosketches may be combined in a single PDF file and uploaded as the designated attachment type.

**Note:** If the NIH has modified the NIH Biosketch, applicants may use the newly modified template, or the template provided in ProposalCentral.

## 11. OTHER SUPPORT (PAGE 6.1)

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 to sign their Other Support document.

Provide the following information for the PI:

**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 Yosemite and the ACS). Provide for each award:

- a. Source of funds
- b. Grant number
- c. Project title
- d. Inclusive dates of approved or proposed project. For example, in the case of NIH support, provide the dates of the approved or proposed competitive segment.
- e. Total direct costs
- f. Role (e.g., PI, co-PI, co-I, etc.) and percent effort or person-months. For an active project, use person months, even if unsalaried for the current budget period. Classify person-months as academic, calendar, and/or summer.

- g. An outline of the goals of the project in a brief paragraph.
- h. A clear indication of overlap and differences between this grant and the proposed study. If necessary, include an explanatory letter in the Appendix.

**B. Pending Support.** List all pending applications for funding from intramural and extramural sources (e.g., institutional awards and grants from for-profit and not-for-profit agencies, including other grants from Yosemite and the ACS).

- a. Source of funds
- b. Project title
- c. Inclusive dates of approved or proposed project. For example, in the case of NIH support, provide the dates of the approved or proposed competitive segment.
- d. Total direct costs
- e. Role (e.g., PI, co-PI, co-I, etc.) and percent effort or person-months. Classify person-months as academic, calendar, and/or summer.
- f. An outline of the goals of the project in a brief paragraph.
- g. A clear indication of overlap and differences between this grant and the proposed study. If necessary, include an explanatory letter in the Appendix. In such cases, you may accept only one award if both are approved for funding.

**C. Institutional Support**

- a. Details of the institutional commitment to support the applicant's salary and research program, which could include start-up funding.
- b. A description of the space committed to the project.
- 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.

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

Provide a list of collaborators, co-investigators, and consultants using the template. Then upload the letter from each individual collaborator, co-I, or consultant. The letter should outline the role that each person will play with sufficient detail for evaluation of the value of the individual contribution. The list and the letters may be combined in a single PDF file and uploaded as the designated attachment type.

## **13. COMPLIANCE STATEMENTS (PAGES 8.1 – 8.2)**

For applicants performing research that does not involve humans/exempt or involves vertebrate animals, check the box on the template that most appropriately describes your research.

### **Human Subjects**

**Selection of study population.** When conducting research on humans, provide the rationale for selecting your study population. Exclusions of any group based on age or other population characteristics must be scientifically justified. Specify the involvement of children, prisoners, and any vulnerable populations. Note: The institution is required to ensure IRB approval is obtained for the grant to start.

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)
40% AA	80 (200 x 0.40)
10% Asian	20 (200 x 0.10)

**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 study participants and what materials will be collected. List any specific non-biological data, such as demographic information, and how it will be collected, managed, and protected. Specify who will have access to such data and what measures you will maintain to keep personally identifiable private information confidential.

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

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

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

### **Vertebrate Animals**

Note: IACUC approval must be obtained before an approved grant can be activated.

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 funds from this award 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.

#### **14. STATEMENT OF INSTITUTIONAL SUPPORT (PAGE 9.1)**

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

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

Non-tenure track applicants should also include a more detailed description of the space committed to the project. For clinician scientists, a description of their clinical practice (discipline and clinical responsibilities) as well as the amount of protected time should also be included.

#### **15. APPENDIX TO APPLICATION**

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

Appended materials may include:

- Additional letters of support
- Recent reprints or preprints (optional)
- Clinical protocols (if applicable)
- Logic model for program projects and dissemination and implementation (if applicable)

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

### **III. REVIEWER GUIDELINE CRITERIA**

Reviewers provide feedback on the following criteria, focusing on the strengths and weaknesses of the proposal. These are meant as general guidelines and are provided here as an aid for preparing your application.

#### **1. ALIGNMENT WITH THE SCIENTIFIC SCOPE OF AWARD**

Evaluate the alignment of the application with the intent and scientific scope of the funding announcement.

#### **2. INVESTIGATOR/RESEARCH TEAM**

Does the PI and research team have the training and experience needed to carry out the proposed research? Provide an overall evaluation of their academic, clinical, and/or scientific qualifications. Do team members have complementary skills and a feasible plan for collaboration, where applicable?

#### **3. REPLY TO PREVIOUS REVIEWS [IF APPLICABLE]**

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

#### **4. RESEARCH PLAN**

These awards are intended to support exploratory projects and test high risk/high reward ideas that establish feasibility. To that end, are the overall strategy, methods, data collection, analyses, and timeline well-reasoned and appropriate to accomplish the specific aims of the project? Where appropriate, are proposed recruitment and/or case ascertainment methods well developed? Is the sample size adequate? Are potential pitfalls, alternative approaches, benchmarks for success, and future plans articulated? Is there enough information provided to understand the analytical plan, methods, and technologies?

#### **5. SIGNIFICANCE AND CANCER RELEVANCE**

Does the project address an important problem or a critical barrier to progress? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field? How might this research impact persons at risk for, or living with, cancer and their family members and/or caregivers? If appropriate, describe how the project contributes to promoting cancer health equity? The relevance to cancer may be indirect and/or long-term, but the connection must be clearly articulated by the applicant.

#### **6. INNOVATION**

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

#### **7. ENVIRONMENT AND RESOURCES**

Will the scientific environment, resources, and institutional support contribute to the probability of success? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements? For early-stage investigators, are there competitive start-up funds to support the candidate's independent research program?

#### **8. BUDGET**

**NOT TO BE FACTORED INTO SCORING**

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

## **9. COMPLIANCE STATEMENTS**

### **NOT TO BE FACTORED INTO SCORING**

- **Human Subjects:** If applicable, evaluate the plans for protection of human subjects from research risks justified in terms of the scientific goals and research strategy proposed. For example, are the potential benefits and risks to subjects articulated reasonable and appropriate given the study design? Are the plans for conducting sub-analysis by group, data security and confidentiality, biohazards and data and safety monitoring adequate?
- **Inclusion of Women, Minorities, and Children:** When the proposed project involves human subjects, evaluate the adequacy of the proposed plans for inclusion or exclusion of minorities, male and female genders, as well as children.
- **Vertebrate Animals:** Evaluate the plan for live, vertebrate animals as part of the scientific assessment according to the following points: 1) necessity for the use of the animals and species proposed; 2) appropriateness of the strains, ages, and gender; 3) justifications for, and appropriateness of, the numbers of animals.
- **Biohazards:** Assess whether materials or procedures proposed are potentially hazardous to research personnel and/or the environment, and if needed, determine whether adequate protection is proposed.

## **APPENDIX A: EXAMPLES OF GENERAL AUDIENCE SUMMARIES**

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

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

Title: Regulation of Chromosome Segregation in Human Cells

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

## APPENDIX B: EXAMPLE OF STRUCTURED TECHNICAL ABSTRACT

Title: Structure and Function of DNA Replication Origins in Yeast

**Background:** The initiation of DNA replication marks a crucial step in the eukaryotic cell cycle. Entering S phase commits the cell to a full round of cell division. Studies in the budding yeast, *Saccharomyces cerevisiae*, have driven the field during the past decade, although our data and work by others suggest that many aspects of DNA replication are highly conserved in all eukaryotes, including humans. Origin structure has been best described for autonomously replicating sequence (ARS) function. Different origins have a different domain organization, and it is unclear how these differences impact the initiation of DNA replication. Recently, we have shown that initiation events occur at distinct nucleotide positions in yeast, a feature that appears to be conserved in humans.

**Objective/Hypothesis:** Our preliminary studies indicate that origin organization dictates where replication initiates. Therefore, we propose to define how features of ARS elements contribute to the precise initiation mechanism.

**Specific Aims:** (1) To determine whether chromosomal origins other than ARS1 initiate DNA replication at a distinct site; (2) to identify what determines the replication start point within origins; and (3) to determine if chromatin structure affects the initiation pattern at ARS elements.

**Study design:** Using a technique that we have recently developed, replication initiation point mapping, we will first map the nucleotide positions at which replication initiates in wild-type and mutant ARS elements. To address the issue of what role chromatin configuration plays in origin activation, we will analyze the nucleosome organization of different ARS loci in relation to those regions where the parental DNA double-strand unwinds first. We will correlate the sites of initiation with sites of unwinding and place those into context with the overall chromatin structure at a given chromosomal ARS locus.

## APPENDIX C: CLASSIFICATION CATEGORIES - AREAS OF RESEARCH

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

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

Applicants are asked to select from the following codes:

### 1 – BIOLOGY

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

#### 1.1 Normal Functioning

*Examples of science that would fit:*

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

#### 1.2 Cancer Initiation: Alterations in Chromosomes

*Examples of science that would fit:*

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

#### 1.3 Cancer Initiation: Oncogenes and Tumor Suppressor Genes

*Examples of science that would fit:*

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

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

#### 1.4 Cancer Progression and Metastasis

*Examples of science that would fit:*

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

#### 1.5 Resources and Infrastructure

*Examples of science that would fit:*

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

## 2 – ETIOLOGY

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

## 2.1 Exogenous Factors in the Origin and Cause of Cancer

*Examples of science that would fit:*

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

## 2.2 Endogenous Factors in the Origin and Cause of Cancer

*Examples of science that would fit:*

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

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

Examples of science that would fit:

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

## 2.4 Resources and Infrastructure Related to Etiology

*Examples of science that would fit:*

- Informatics and informatics networks; for example, patient databanks

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

### **3 – PREVENTION**

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

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

Examples of science that would fit:

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

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

*Examples of science that would fit:*

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

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

### **3.3 Chemoprevention**

*Examples of science that would fit:*

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

### **3.4 Vaccines**

*Examples of science that would fit:*

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

### **3.5 Complementary and Alternative Prevention Approaches**

*Examples of science that would fit:*

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

### **3.6 Resources and Infrastructure Related to Prevention**

*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/personalized medicine.

##### **4.1 Technology Development and/or Marker Discovery**

*Examples of science that would fit:*

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

##### **4.2 Technology and/or Marker Evaluation with Respect to Fundamental Parameters of Method**

*Examples of science that would fit:*

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

##### **4.3 Technology and/or Marker Testing in a Clinical Setting**

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

## 5.4 Systemic Therapies - Clinical Applications

*Examples of science that would fit:*

- Clinical testing and application of treatments administered systemically such as cytotoxic or hormonal agents, novel systemic therapies such as immunologically directed therapies (treatment vaccines, antibodies, antibiotics, theranostics or other biologics), gene therapy,

angiogenesis inhibitors, apoptosis inhibitors, whole body hyperthermia, bone marrow/stem cell transplantation, and differentiating agents, adjuvant and neo-adjuvant treatments, systematically-delivered nanoparticles/microsomes, cell-based therapies, manipulation of the microbiome etc.

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

## **5.5 Combinations of Localized and Systemic Therapies**

*Examples of science that would fit:*

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

## **5.6 Complementary and Alternative Treatment Approaches**

*Examples of science that would fit:*

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

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

*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.