



**AMERICAN CANCER SOCIETY – FLATIRON HEALTH REAL-WORLD
DATA IMPACT AWARD**

**POLICIES AND INSTRUCTIONS
EFFECTIVE JANUARY 2023**

ELECTRONIC APPLICATION DEADLINE: April 3, 2023

**AMERICAN CANCER SOCIETY, INC.
Extramural Discovery Science**

Web site: <http://www.cancer.org>

Email: grants@cancer.org

MISSION

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



AMERICAN CANCER SOCIETY POLICY ADDENDUM

1. APPLICATION DEADLINE

Applications for grants must be submitted electronically via proposalCENTRAL. Since applications will only be accepted from investigators who submitted a letter of intent (LOI) and were invited to apply, access to application materials is available using the link provided in the American Cancer Society invitation to apply (see Instructions). Electronic applications must be submitted through the proposalCENTRAL website by 11:59 PM EST on the specified deadline date. No supplemental materials will be accepted after the deadline unless requested by staff for administrative purposes or when requested by the reviewers.

KEY DATES: DEADLINE, REVIEW, NOTIFICATION, AND ACTIVATION SCHEDULE

Application Deadline	Peer Review Meeting	Award Notification	Grant Activation
April 3, 2023	June 2023	September 2023	January 1, 2024

2. ELIGIBILITY

- Current or former ACS grantees conducting health services, health policy research, or public health with requisite expertise to conduct research projects using de-identified real-world data. Those meeting the requirements will be sent invites through proposalCENTRAL.
- Applicants must have an active ACS grant or a completed ACS grant that expired between January 2019 and December 2022.
- An eligible current/former ACS grantee may mentor a qualified doctoral-level research team member (e.g., a postdoc in the ACS grantee’s lab), who can serve as the project PI. This lab member should have the training and expertise to work with real-world data.
- Applicants who received a Flatiron Health Real World Data Impact Award in 2020-2022 are not eligible.
- Applications may be submitted by a college, university, medical school, or other not-for-profit research organization within the United States, its territories and the Commonwealth of Puerto Rico.

3. GRANT TERMS

The maximum allowable budget is \$75,000 direct cost only, for a 1-year period. No resubmissions are allowed. These grants are not renewable. All Grantees shall be subject to the terms and conditions of a separate non-disclosure confidentiality agreement between Flatiron Health, Inc. (FHI) and the Grantee’s Institution. All awardees will be required to comply with the FHI data use agreement which outlines the terms and conditions required for the Grantee’s use, receipt and storage of FHI licensed data. **Awarded institutions will continue to adhere to the ACS Terms and Conditions in place for an existing or former grant-in-effect and as stated in the [ACS Policies for All Grants](#).**



**ACS FLATIRON HEALTH REAL WORLD DATA IMPACT AWARD APPLICATION
INSTRUCTIONS**

TABLE OF CONTENTS

I.	GENERAL INFORMATION	4
1.	THE GRANT APPLICATION SYSTEM.....	4
2.	APPLICATION FORMAT	4
3.	UPDATES OF INFORMATION	5
4.	REQUIRED INFORMATION	5
5.	GENERAL AUDIENCE SUMMARY	7
6.	STRUCTURED TECHNICAL ABSTRACT	8
7.	STATEMENT OF CANCER RELEVANCE AND IMPACT	8
10.	ASSURANCES AND CERTIFICATION.....	9
II.	APPLYING.....	9
A.	APPLICATION SUBMISSION AND REQUIRED E-SIGNATURE	9
B.	APPLICATION TEMPLATES	10
1.	TABLE OF CONTENTS (PAGE 1.1)	10
2.	BIOGRAPHICAL SKETCH OF APPLICANT (PAGE 2.1)	10
3.	RESEARCH PLAN AND ENVIRONMENT (PAGE 3.1)	10
4.	DETAILED BUDGET.....	11
5.	JUSTIFICATION OF BUDGET.....	12
6.	BIOGRAPHICAL SKETCHES OF KEY PERSONNEL (PAGE 4.1)	13
7.	OTHER SUPPORT (PAGE 5.1).....	13
8.	LIST OF LETTERS OF SUPPORT FROM COLLABORATORS/CONSULTANTS (PAGE 6.1)	14
9.	COMPLIANCE STATEMENTS (PAGE 7.1-7.3)	15
10.	STATEMENT OF INSTITUTIONAL SUPPORT (PAGE 8.1).....	15
11.	APPENDIX TO APPLICATION	16
III.	REVIEWER GUIDELINE CRITERIA	16
	APPENDIX A: CLASSIFICATION CATEGORIES - AREAS OF RESEARCH.....	18
	APPENDIX B: EXAMPLES OF PROJECT ALIGNMENT TO RESEARCH PRIORITIES.....	31

I. GENERAL INFORMATION

1. THE GRANT APPLICATION SYSTEM

Once your LOI is approved in proposalCENTRAL, an application will be created for you. The application is in the active “proposals” section of your proposalCENTRAL account.

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

a. The key steps for starting an application:

- **Create Application Title:** Click on “Edit,” enter the same Project Title as the LOI Title, and click SAVE.
- **Save Application:** Once you have clicked on the “Save” button, the links to the other pages of the application appear in the Proposal Sections menu.

b. Enable Other Users to Access this Proposal: Allow others (e.g., institutional administrators or collaborators) to view, edit, e-sign, or submit your proposal.

c. Technical Assistance: Detailed information is available through tutorials provided on the proposalCENTRAL login page. If you have problems accessing or using the electronic application process, click on “Help” or contact ALTUM Customer Service at pcsupport@altum.com or 1-800-875-2562.

2. APPLICATION FORMAT

- Insert PI name in the header for each template of the application. Do not change the footers on the templates.
- **Type size:** Use 12-point Times New Roman or 11-point Arial as the minimum font size for the text of the application. A 10-point Times New Roman or 9-point Arial font type may be used for figures, legends, and tables.
- Applications may be single- or double-spaced (if single spacing, enter a space between paragraphs).
- **Margins:** ≥ 0.5 inches all around unless a form with different margins is supplied in the application templates.
- **Cover Pages:** The first few pages of the application are considered cover pages and are not numbered. The cover pages include the Title/Signature Page, Contact Page, General Audience Summary, Statement of Cancer Relevance and Impact, Structured Technical Abstract, Priority Area Selection and Justification, Budget, Budget Justification, and Subcontractor Budget & Justification.
- **Numbered Sections:** Number the pages in the upper right corner according to the proposal sections listed in the Table of Contents.



- **Do not number:** Signature page, Contact page, General Audience Summary, Structured Technical Abstract, Statement of Cancer Relevancy and Impact, Justification of Alignment with Research Priorities, Budget & Justification, or the Appendix.

3. UPDATES OF INFORMATION

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

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

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

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

4. REQUIRED INFORMATION

Project Title: Do not exceed 150 characters including spaces; avoid abbreviations if possible.

Note: The title will truncate after 81 characters on the title page.

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

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.

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

Citizenship Status: On proposalCENTRAL under “Professional Profile”, indicate your current citizenship status and country of citizenship. There are no citizenship restrictions.

Project Coding: Donors frequently have an interest in funding 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: Project coding is not considered at peer review.**

Project Period and Budget: ACS FHI Real-World Data Impact Award may not exceed \$75,000 direct cost for a 1-year award period, no indirect costs are allowed. The project start date is January 1, 2024.

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 front page if required by the institution, but this is not required by ACS for submission. The PI must give the Institutional Official access to the application for e-signing to be completed. 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 reporting all IP updates to the ACS should the project be awarded funding.

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

Key Personnel: 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. Key Personnel can include individuals at the master’s or baccalaureate level (such as graduate students and research assistants) if they meet this definition. “Zero percent” or “as needed” are not acceptable levels of involvement. **The PI is always considered Key Personnel, but do not list them under key personnel on proposalCENTRAL.**

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, if paid ^b	Yes, if paid ^c	Letter of Agreement/Support ^b
	No	No	No	Yes, if paid	
Other	No	No	No	Yes	No

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

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

^c If key personnel are not being paid, include 'in kind' for dollar amount; percent effort is required. Note that the percent effort indicated on the budget tool in proposalCENTRAL can be different than requested compensation.

- 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. **NOTE: If the PI is a trainee/research team member the eligible ACS grantee, then the eligible ACS grantee must be listed as a Co-I on the project (compensation is not required but their role must be outlined in the budget justification and in their support letter).**
- A **Collaborator** plays a lesser role in the thinking and logistics of the project than a Co-Investigator. Depending on the role and effort, a collaborator may be designated as Key Personnel and may be compensated.
- A **Consultant** provides expert advice most often for a fee. If the consultant contributes to the scientific development or execution of a project substantively and measurably, he or she should be designated as Key Personnel.
- **Other** is defined as individuals who are compensated for their contribution to the project but are not considered Key Personnel (e.g. student assistants, technical staff).

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 committees as well as to several general audiences, including donors. **Avoid the use of technical jargon.**

This section is limited to **1500 characters**, including spaces. Describe how the project contributes short- and long-term to the control of cancer. For basic studies relying on experimental models (rather than human cancer cells, tissues, or clinical data) explain how the successful completion of the proposed work will lead to a better understanding of the disease or improve our ability to prevent, detect, treat or manage cancer or cancer patients.



For studies involving human subjects, what do you expect to learn about how access to care impacts the overall cancer burden? How could your study improve both delivery of care and cancer outcomes? What effects do you anticipate on the morbidity, mortality, and/or quality of life of your study population? How might further investigations find potential value for health policy?

8. JUSTIFICATION OF PROJECT ALIGNMENT TO RESEARCH PRIORITIES

Explain how your proposed project aligns to the selected research priority/priorities. If your project aligns to multiple priority areas, provide additional justification of the alignment to those areas in this section as well. Please make sure that the priority area or areas are noted in the statement. This section is limited to **1500 characters**, including spaces. Note: If the character limit is exceeded in this section, which is evaluated, it will be truncated. Examples of research priority alignment statements are provided in Appendix B.

9. SELECTION OF RESEARCH PRIORITIES

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

10. ASSURANCES AND CERTIFICATION

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

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

For funded grants, it is the responsibility of the institution to immediately report to ACS any action including recertification or loss of IRB approval which may occur during the term of the award that is related to the work described in the grant application. In addition, prior to grant activation a Flatiron Health, Inc (FHI) Data Use Agreement (NDA) must be signed by the PI and submitted to FHI.

II. APPLYING

A. APPLICATION SUBMISSION AND REQUIRED E-SIGNATURE

We do not accept paper copies of applications.

- All application attachments, including the Appendix, must be uploaded as .pdf documents.
- Validate the application on proposalCENTRAL. An application that has not been validated cannot be electronically submitted.



- Applications must be electronically submitted on proposalCENTRAL by **11:59 PM ET on Monday April 3, 2023**. 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: You will not be able to make any changes to the forms or upload any modifications to the files after submission.

B. APPLICATION TEMPLATES

An application consists of several sections that must be uploaded before submission. Templates for these sections are available once an application is started on proposalCENTRAL. The templates must be downloaded and completed offline. Completed templates must be converted into PDF documents before uploading to corresponding sections.

1. TABLE OF CONTENTS (PAGE 1.1)

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

2. 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.

3. RESEARCH PLAN AND ENVIRONMENT (PAGE 3.1)

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

- A. Hypothesis and Specific Aims.** List the hypotheses, objectives, and goals of the research proposed and describe the specific aims briefly. In addition, state the anticipated impact of the research on some aspect of the cancer continuum: prevention, early detection, treatment, or survivorship.
- B. Background and Significance.** Concisely summarize and critically evaluate related work done by others. The critique of the literature should also include pertinent evidence that informs your approach and should address critical gaps in knowledge. Additionally, the model(s) that underpin(s) the research approach and forms the basis of your conceptual framework should be summarized here. If aims are realized, how will the results of this study impact cancer patients, clinical practice, the public's health and/or policy?
- C. Innovation.** Provide a rationale for why this proposed research is novel/innovative.
 - Describe how the research proposes meaningful improvements or addresses critical gaps.

- Explain how the application challenges and seeks to shift current research or paradigms.
- Describe any novel theoretical concepts, approaches or methodologies, to be developed or used, and any advantage over existing methodologies.

D. Preliminary Studies and Previous Experience. Provide results of research accomplished by you that are relevant to this proposal; reprints or preprints may be included in the appendix. **Note:** The entire application is considered confidential, including reports of unpublished research.

E. Research Design and Methods. Describe your overall hypothesis, proposed methods, procedures, and data analysis in sufficient detail to permit evaluation by other scientists; include your rationale for approaches and analysis. 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. Environment. Describe briefly the space and equipment available for you to carry out the proposed research project. Investigators must have an institutional commitment of research facilities. This section is of major importance for applicants whose appointment is not in the tenure stream.

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

4. DETAILED BUDGET

The maximum allowable budget is \$75,000 direct cost for a 1-year period, no indirect costs are allowed.

A. Personnel. Names and positions of all key personnel must be individually listed and the percentage of time to be devoted to the project by each person should be noted, even when salary is not requested. List all Key Personnel (defined as individuals who will participate actively in the design and/or execution of the studies) other than the PI. Details of contractual arrangements with collaborators should be provided in the Justification of Budget section of the application.

If the individual has not been selected, please list as "vacancy." Personnel may receive salary support up to a maximum that equals the National Cancer Institute salary cap, prorated per their percent effort on the project. If a Key Person is not receiving salary, you can request \$0 for salary, but their percent effort is still required. Their effort and contribution to the project should be outlined in the Budget Justification even if they are not being compensated.

The costs to the institution of employee fringe benefits should be indicated as a percent of the employee's salary. The amount of fringe benefits requested must be prorated to the salary requested. For example, if 5 percent of an individual's annual salary is requested

then no more than 5 percent of that individual's annual cost for fringe benefits can be requested.

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

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.
- **Small or expendable equipment** – Defined as expendable property with a purchase cost per unit that is less than \$5,000 and/or that has a short service life (<1 year).
- **General purpose equipment** – Equipment such as computers or laptops used primarily or exclusively in the actual conduct of the proposed scientific project.

C. Supplies. Group into major categories.

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

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

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

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

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

G. Indirect Costs. Indirect costs are not allowed.

H. Total Amount Requested. Budget totals should reflect a maximum duration of 1 year. Enter the total amount requested and round to the nearest thousand dollars.

5. JUSTIFICATION OF BUDGET

Provide budget justification on the template. Justify all items of permanent equipment costing over \$5,000, as well as your needs for personnel, supplies, travel, and other miscellaneous items. If the budget includes a request for funds to be spent outside the United States or its territories, explain why these funds are essential to the successful conduct of the project, and



why there are no alternatives. Provide details of contractual arrangements with key personnel in this section.

6. BIOGRAPHICAL SKETCHES OF KEY PERSONNEL (PAGE 4.1)

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

7. OTHER SUPPORT (PAGE 5.1)

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

Exceptions:

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

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

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

- a. Source of funds: the organization providing the support
- b. Grant number
- c. Project title
- d. Inclusive dates of approved or proposed project. For example, in the case of NIH support, provide the dates of the approved or proposed competitive segment.
- e. Total direct costs
- f. Percent effort or person-months. For an active project, use person months, even if unsalaried, for the current budget period. Classify person-months as academic, calendar, and/or summer.
- g. An outline of the goals of the project in a brief paragraph.
- h. A clear indication of overlap and differences between this grant and the proposed study. If necessary, include an explanatory letter in the Appendix.

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

- a. Source of funds: the organization providing the support
- b. Project title



- c. Inclusive dates of approved or proposed project. For example, in the case of NIH support, provide the dates of the approved or proposed competitive segment.
- d. Total direct costs
- e. Percent effort or person-months. For an active project, use person months, even if unsalaried, for the current budget period. Classify person-months as academic, calendar, and/or summer.
- f. An outline of the goals of the project in a brief paragraph.
- g. A clear indication of overlap and differences between this grant and the proposed study. If necessary, include an explanatory letter in the Appendix. In such cases, you may accept only 1 award if both are approved for funding. The American Cancer Society does not negotiate partial funding of grants with overlapping specific aims.

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

C. Institutional Support. Provide the following information for the Principal Investigator only:

- a. A description of any start-up funds provided by the institution to the applicant. An award of start-up funds does not decrease the likelihood of ACS support and can be important evidence of institutional commitment.
- b. Details of the institutional commitment to support the applicant's salary.
- c. The current term of the applicant's appointment.

These details should be confirmed by the Department Chair in the Statement of Institutional Support included in Section 10, below.

Non-tenure track applicants should also include a more detailed description of the space committed to the project. If the applicant is in the same department as a previous mentor, provide information on the relationship between the mentor's research space, and the space available for the project, and the relationship between funded research projects in the mentor's laboratory and the present application. Documentation should be included in the Statement of Institutional Support (Section 10, below) written by the Department Chair.

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

Provide a list of collaborators/consultants. Then upload the letter from each individual collaborator or consultant in proposalCENTRAL. The letter should outline the role that person will play with enough detail for evaluation of the value of the individual contribution. **NOTE: If the PI of the grant is a trainee/research team member of the eligible ACS grantee, then the mentor must include a letter of support, including their support of the project, role, and the mentoring that will be provided to the PI.**



9. COMPLIANCE STATEMENTS (PAGE 7.1-7.3)

Human Subjects

Selection of study population: When conducting research on humans, provide the rationale for selecting your target population. Include the involvement of children, minorities, and especially vulnerable populations such as neonates, pregnant women, prisoners, institutionalized individuals, or others who may be considered vulnerable populations or others who may be considered vulnerable populations. 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 non-human subjects' research please check the box that most appropriately describes your research.

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

Research specimens and data: If the proposed research involves biospecimens, explain how the research material will be obtained from living subjects and what materials will be collected. List any specific non-biological data from human subjects and how it will be collected, managed, and protected (e.g., demographic data elements). Specify who will have access to such data and what measures will be implemented to keep personally identifiable private information confidential.

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

10. STATEMENT OF INSTITUTIONAL SUPPORT (PAGE 8.1)

Include a letter from the Department Chair or equivalent that clearly indicates the institution's commitment to support the applicant and their research program. Details should include salary

support, dedicated space, startup funds, and others as appropriate. Clinician scientists should include a description of their clinical practice (discipline and clinical responsibilities) as well as the amount of protected time. The letter should also describe the Department's long-term goals for the applicant's career. **NOTE:** *If the PI is a trainee/research team member of the eligible ACS grantee, then this letter should be tailored to the career stage and position of the applicant.*

11. 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:

- FHI signed NDA (required)
- Letters of support from collaborators/consultants
- Recent reprints or preprints (optional)

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

1. ALIGNMENT WITH ACS RESEARCH PRIORITY AREAS

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

2. PROJECT OVERVIEW

Provide a brief overview of the project.

3. SIGNIFICANCE AND CANCER RELEVANCE

Does the project address an important problem or a critical need/barrier to progress in the field? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or some aspect of the cancer continuum be impacted? How is this research relevant to persons at risk for or living with cancer and their family members, caregivers, friends, and community?

4. INNOVATION

Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions?

5. INVESTIGATORS/RESEARCH TEAM

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

6. APPROACH



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

7. ENVIRONMENT AND RESOURCES

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

8. LIKELIHOOD OF SUCCESS

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

9. BUDGET

NOT TO BE CONSIDERED IN SCORING

Evaluate the overall budget and individual budget categories with respect to the award cap and the project aims. Are the budget items justified, specified, and accurate? Is the project duration and the percent effort of key personnel appropriate? Is there a potential overlap with the PI's other funded research? If the budget includes a request for funds to be expended outside the United States or its territories, include an explanation of why such costs are essential for the successful conduct of the project, and why there are no alternatives. Describe any suggested budget changes using specific amounts or percentages.

10. COMPLIANCE STATEMENTS

NOT TO BE CONSIDERED IN SCORING

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

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

11. OVERALL RECOMMENDATIONS

Briefly summarize your critique and state your level of enthusiasm using one of these descriptive terms: Outstanding, Excellent, Good, Fair, or Not Competitive.

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, 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.

APPENDIX B: EXAMPLES OF PROJECT ALIGNMENT TO RESEARCH PRIORITIES

Example 1

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

Selection of Priorities

Screening and Diagnosis: 100%

Example 2

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

Selection of Priorities

Etiology: 25%

Screening and Diagnosis: 25%

Treatment: 50%

Example 3

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



analysis will also be used to identify proteins specific to acute leukemia that may be targeted therapeutically (Treatment).

Selection of Priorities

Screening and Diagnosis: 85%

Treatment: 15%

Example 4

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

Selection of Priorities

Treatment: 100%

Example 5

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

Selection of Priorities

Etiology: 20%

Treatment: 80%

Example 6

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

Selection of Priorities

Survivorship: 100%

Example 7



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

Selection of Priorities

Health Equity: 100%

Example 8

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

Selection of Priorities

Screening and Diagnosis: 100%