REQUEST FOR RESEARCH IDEAS
TO CONTRIBUTE TO THE ASCO RESEARCH PORTFOLIO

Issue Date: August 22, 2019
Response Deadline: September 30, 2019

ASCO Center for Research and Analytics (CENTRA)
Research Administration Unit (RAU)
Inquiries, questions, and requests for clarification related to this request can be emailed to ResearchIdeas@ASCO.org.
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1. ASCO Overview

Founded in 1964, the American Society of Clinical Oncology, Inc. (ASCO®) is committed to making a world of difference in cancer care. As the world’s leading organization of its kind, ASCO represents more than 45,000 oncology professionals who care for people living with cancer. Through research, education, and promotion of the highest-quality patient care, ASCO works to conquer cancer and create a world where cancer is prevented or cured, and every survivor is healthy. ASCO is supported by its affiliate philanthropic organization, Conquer Cancer, and includes a wholly owned subsidiary, CancerLinQ®. Learn more at www.ASCO.org, www.conquer.org, and www.cancerlining.org, explore patient education resources at www.Cancer.Net, and follow us on Facebook, Twitter, LinkedIn, and YouTube.

The ASCO Center for Research & Analytics (CENTRA®) is issuing this request for research ideas. CENTRA serves as the hub of ASCO research activities to conduct, enable, and define standards for oncology research. CENTRA makes select ASCO data assets available to the oncology community for research purposes. Since its founding, ASCO has been committed to advancing the field of oncology and improving cancer care through the dissemination and application of high-quality evidence. CENTRA’s mission is generating, integrating, analyzing, and sharing oncology data to foster innovation in research and patient care. CENTRA conducts or enables ASCO-sponsored research; develops standards, resources, and tools for the conduct of clinical cancer research; and serves as a data management and analysis hub in support of ASCO’s mission. The Center supports research studies conducted internally and through external collaborations. CENTRA helps create an evidence base that can inform the development of cancer policy, advance the practice of oncology, and improve cancer care for patients.
2. Background and Opportunity

The American Society of Clinical Oncology, Inc. (ASCO®) Center for Research and Analytics (CENTRA®) is issuing this request for research ideas to:

1. Announce the ASCO Board-approved Scope and Methods of ASCO Research, and

2. Solicit ideas for high-priority research projects that ASCO should consider conducting.

At its March 2019 meeting, the ASCO Board approved a scope of ASCO research that includes several elements that are included in this document.

1. Guiding principles and criteria for prioritization of ASCO Research projects,
2. Scope of ASCO Research, and
3. Methods employed in ASCO Research.

The ASCO Board defined an ASCO research project as

A project intended to develop generalizable new knowledge designed, conducted, and/or analyzed by ASCO volunteers (i.e., members working in a volunteer-capacity on ASCO committees, councils, and task forces) and/or staff on behalf of ASCO, or collaboratively between ASCO and other entities.

Respondents to this request for research ideas should consider the priorities that ASCO has articulated in three different venues:

2. ASCO’s 2019 policy priorities (www.asco.org/advocacy-policy/policies-positions-guidance/policy-priorities),

CENTRA will prepare a report to the ASCO Board of Directors regarding research ideas received, reviewed, approved, and selected for implementation. ASCO will also publicly release a summary of research ideas submitted.
3. Important Information for Research Idea Respondents:

- This request for research ideas is not intended to convey a commitment by ASCO to undertake a research project. ASCO decisions to launch ASCO Research Projects are dependent, in part, on availability of research funding outside of the ASCO budget and/or other resources necessary to conduct the project (i.e., ASCO is neither offering nor committing to fund research projects).

- By responding to this request, the respondent is freely contributing the research project concept to ASCO.

- If a submitted project is selected for implementation, the project submitter will have the opportunity to indicate an interest in participating as part of the ASCO Research project team. ASCO Research projects may provide many opportunities for ASCO member engagement. For example, ASCO members could serve as members of a study group or data safety monitoring board, site investigator, research advisor, or principal or co-principal investigator. This goal is consistent with ASCO’s organizing principles as a membership organization.

- ASCO will work with volunteer members (specifically, the ASCO Cancer Research Committee) to decide which ideas merit further development as ASCO Research projects. Responses that have sound scientific methodology, address ASCO’s Research Priorities, fill important gaps in the evidence base, and advance ASCO’s mission and the Board-approved ASCO Strategic Plan (2019-2023) will be prioritized, provided that sufficient external resources are secured, and staff resources are available.

- This request for ideas does not indicate an intent on the part of ASCO to provide funding for ASCO Research projects. Launch of any ASCO Research project will depend on ASCO’s ability to secure external funds to support the research project.

- The respondent grants to ASCO, as a condition of submission of information in response to this request, that the information and ideas contained are freely given to ASCO for consideration in its research planning and execution.
4. Guiding Principles for Prioritizing ASCO Research

ASCO Research projects should:
- Pursue research questions that ASCO is uniquely poised to address
- Fill knowledge gaps that are clinically meaningful to patients and providers
- Inform ASCO policy development
- Build on and enhance ASCO’s existing infrastructure (e.g., CancerLinQ, TAPUR, ASCO data assets)
- Employ research methods and tools that are embraced by ASCO and fit for purpose
- Engage patients and their advocates in all aspects of the research process

5. Scope of ASCO Research

The scope of ASCO Research includes projects that are within the general categories or topical areas described below and that comport with the Board-approved guiding principles (see section 4).

- **Dissemination and Implementation Research**
  
  **Description:** This category includes research aimed at measuring the translation of knowledge or evidence into clinical practice.
  **Examples:**
  - Influence of practice-changing presentations and publications on care delivery

- **Comparative Effectiveness Research**
  
  **Description:** Research in this category aims to directly compare different therapeutic options to understand the relative benefits, risks, and overall value of the therapies. The results of these studies could be used by patients and clinicians to choose between therapies, by payers to determine coverage policy, and by policymakers to understand societal implications for healthcare programs and spending.
  **Examples:**
  - Comparative studies of two or more U.S. Food and Drug Administration (FDA)-approved indications for the same tumor type and line of therapy
  - Studies of treatment efficacy and safety in disparate populations not included in clinical trials

- **Practice of Medicine Research**
  
  **Description:** This category encompasses research that examines variations in medical practice and how practicing clinicians adapt evidence from clinical trials into routine clinical practice.
  **Examples:**
  - Targeted Agent and Profiling Utilization Registry (TAPUR) Study ([www.tapur.org/](http://www.tapur.org/)) – understanding the utility and impact of genomic testing and consequent off-label targeted drug use
  - Drug dosing and symptom management in real-world populations
Treatment sequencing when multiple possible options exist, such as checkpoint inhibitors and targeted therapies

- **Health Services Research**
  **Description:** This category includes research about the oncology clinician workforce, the organization of oncology practices, and delivery of cancer care. Included in this category is the “Cancer Care Delivery Research” defined by the U.S. National Cancer Institute (NCI) as “Multidisciplinary science that seeks to improve clinical outcomes and patient well-being by intervening on patient, clinician, and organizational factors that influence care delivery.”
  **Examples:**
  - Patterns of care delivery, especially for disparate populations, deployment of new treatment modalities (e.g., Chimeric Antigen Receptor T-cell therapy (CAR-T) therapy access), and ongoing care of cancer survivors
  - Improving access and quality of cancer care in rural populations
  - Utilization and adherence to oral anticancer agents
  - Economic modeling of alternative payment models in oncology
  - Collaboration models to promote communication across the oncology care team

- **Research on Research Methods**
  **Description:** This category includes projects that would help understand the impact of research methods and designs that ASCO recommends.
  **Examples:**
  - Impact of ASCO-Friends of Cancer Research’s eligibility criteria recommendations on enrollment rates and patient diversity in oncology clinical trials (www.asco.org/research-progress/clinical-trials/clinical-trial-eligibility-criteria)
  - Contribution to standard-setting for real-world data analysis and real-world evidence generation and evaluation
  - Separation of signals from the noise of adverse events reported in clinical trials

6. **Methods Employed in ASCO Research**
The methods employed in ASCO Research will be fit-for-purpose and, where possible, will leverage or expand existing ASCO resources and infrastructure.

- **Observational Research**, especially with CancerLinQ Discovery (cancerlinq.org/research-database) – CENTRA and CancerLinQ staff and ASCO volunteers are developing expertise in the analysis of CancerLinQ Discovery data. CancerLinQ Discovery will continue to be a primary observational dataset, but ASCO will likely work with other datasets, as well.

- **Pragmatic Clinical Trials** – The TAPUR Study is ASCO’s example of a pragmatic clinical trial. The site network established (more than 100 research sites across the U.S., including some overlap with CancerLinQ sites) can potentially support other pragmatic studies. ASCO could also embed prospective or
observational studies within CancerLinQ sites and/or PracticeNET sites (practice.asco.org/practice-support/practice-benchmarking/practicenet).

- **Qualitative Research** – ASCO staff have experience in conducting surveys, structured interviews, and/or focus groups. As the ASCO Research program grows, we expect that ASCO will increasingly be able to leverage ASCO staff and external collaborators or vendors to conduct this research.

- **Economic Modeling and Analysis** – ASCO staff have real-world oncology business experience to provide timely analysis of PracticeNET and other economic data, especially to inform proposed changes to public and private policies. ASCO also leverages volunteer expertise and contractual relationships with outside vendors to accomplish this type of analysis. As the ASCO Research portfolio grows, we expect that ASCO will increasingly be able to leverage ASCO staff and external collaborators or vendors to conduct this research.

- **Integration of Large Datasets** – ASCO staff have conducted an inventory of internal ASCO datasets and enhanced ASCO’s facility with publicly available datasets (including Medicare billing data). This expertise is helping to increase ASCO knowledge of the oncology marketplace.

### 7. Potential Roles of ASCO Members in ASCO Research

As a membership organization, ASCO is committed to working closely with its members in the conduct of ASCO programs and projects. As such, ASCO members will have opportunities to participate in ASCO Research. Potential roles range from principal investigator or co-investigator to site investigator, author (including lead and senior authors, as determined by journal standards), research participant (especially in the case of surveys and evaluation of ASCO resources), and committee members. As an example, the ASCO TAPUR study relies on members in many roles, including site investigators, authors, and members of its steering group, molecular tumor board, data and safety monitoring board, and publications group.

### 8. Resources for Respondents’ Consideration


1) **ASCO 2019 Research Priorities to Accelerate Progress Against Cancer**

As the organization that represents and connects the global community of clinicians who discover new treatments for cancer and deliver the latest advances to patients, ASCO included in its 2019 *Clinical Cancer Advances* publication, for the first time, a set of Research Priorities to Accelerate Progress Against Cancer. These priorities represent promising areas of research that urgently need greater attention and have the
potential to significantly improve the knowledge base for clinical decision-making and address vital unmet needs in cancer care.

The 2019 list (below and with additional description and examples in Appendix B) reflects ASCO’s mission—conquering cancer through research, education, and promotion of the highest quality patient care—as well as the diversity of needs and opportunities in oncology. It focuses on cancer prevention strategies, increasing equity in access to and participation in research, optimizing treatment, and improving long-term health for the growing number of cancer survivors around the world. Over time, ASCO’s Research Priorities will evolve with the cancer research landscape and will be updated to reflect advancing science and unmet clinical needs.

**Research Priority 1: Identify Strategies That Better Predict Response to Immunotherapies**
**Description:** Methods to identify patients most likely to benefit from immunotherapy and those at high risk for severe adverse events are urgently needed. The ability to adequately assess benefits and risks of immunotherapy for each individual will lead to better outcomes for patients.

**Research Priority 2: Better Define the Patient Populations That Benefit from Postoperative (Adjuvant) Therapy**
**Description:** It is important to ensure that patients who receive adjuvant therapy are the ones most likely to benefit. Eliminating its use in those who do not benefit will be an important step in optimizing care and eliminating unnecessary adverse effects and costs for patients in whom the benefits are unlikely to outweigh the risks.

**Research Priority 3: Translate Innovations in Cellular Therapies to Solid Tumors**
**Description:** Although cellular therapies that use a patient’s modified cells to harness the immune system are transforming care for some patients with blood-based cancers, there are limited data to show whether this strategy can be expanded to patients with solid tumors.

**Research Priority 4: Increase Precision Medicine Research and Treatment Approaches in Pediatric Cancers**
**Description:** In certain cancers, the use of genomic tools has accelerated development of new targeted therapies that have improved and extended patients’ lives. Despite this success in adult patients, precision medicine treatment approaches have yet to be widely integrated into the treatment of pediatric cancers.

**Research Priority 5: Optimize Care for Older Adults with Cancer**
**Description:** Clinicians face challenges applying clinical trial data to older patients who may have additional health conditions, varying levels of functional ability, and different goals from clinical trial participants. The lack of evidence in this area combined with the inherent diversity of aging populations impedes the delivery of high-quality care for the largest and most rapidly growing segment of patients with cancer.
Research Priority 6: Increase Equitable Access to Cancer Clinical Trials
Description: Additional research is needed to ensure that every patient with cancer, regardless of race, ethnicity, age, geographic location, or socioeconomic status, benefits from research advances.

Research Priority 7: Reduce the Long-Term Consequences of Cancer Treatment
Description: Survivors face long-term consequences of cancer, including adverse effects of cancer therapies that affect quality of life. These adverse effects, which commonly include peripheral neuropathy, cognitive impairment, and cardiotoxicity, pose a substantial burden not only to patients but also to the health care system.

Research Priority 8: Reduce Obesity’s Impact on Cancer Incidence and Outcomes
Description: Obesity is associated with poorer cancer survival and can contribute to increased risk of treatment-related adverse effects. If current trends continue over the next 20 years, it is estimated that obesity will lead to more than 500,000 additional cases of cancer each year in the United States and will surpass smoking as the leading preventable cause of cancer.

Research Priority 9: Identify Strategies to Detect and Treat Premalignant Lesions
Description: Many cancers begin as high-risk lesions that invariably progress to invasive cancer. Currently, little is known about the genetic makeup, heterogeneity, microenvironment, and what causes some of these lesions to progress to invasive cancer. Increased knowledge will help guide new approaches to intercept and eradicate high-risk lesions before their transformation to malignancy.

2) ASCO 2019 Policy Priorities
ASCO’s Government Relations Committee establishes annual policy priorities on an annual basis to reflect emerging issues in cancer care delivery. ASCO develops and evaluates policy topics in an evidence-based way, including generating evidence where none exists. A further description of the priorities is available in Appendix C and online at www.asco.org/advocacy-policy/policies-positions-guidance/policy-priorities.

Policy Priority 1: Pursue access to high quality, affordable care for every patient with cancer

Policy Priority 2: Advance evidence-based policies and delivery system reform that supports oncology providers in their delivery of high quality, high value cancer care

Policy Priority 3: Advocate for policies that support a robust federally funded cancer research, prevention, drug development, and clinical trials system.

3) ASCO Strategic Plan, 2019-2023
ASCO’s strategic plan outlines the Society’s approach to leading the delivery of information and diverse expertise needed by the global oncology community to reduce the burden of cancer. The plan also defines goals that will mark progress towards this outcome. The plan is available on the ASCO website at www.asco.org/about-asco/asco-overview.
9. Review and Prioritization of Proposed Research Projects

ASCO will use the Guiding Principles (see section 4), ASCO’s Strategic Plan and Research Priorities, and the following criteria to review and prioritize proposed research projects.

- Scientific quality of the proposal,
- Expertise of the research team,
- Potential to address evidence gaps in care, improve quality of care, and/or enhance practice health,
- Innovation,
- Feasibility,
- Availability of funding and necessary data, and
- Proposed dissemination and implementation plans.

Research ideas will be submitted to the ASCO Research Administration Unit (RAU) which will conduct an initial review to determine if the proposal is within the Board-approved ASCO Research Scope and comports with ASCO’s Mission and Guiding Principles to Prioritize Research. The RAU is a cross-functional unit organized by CENTRA to coordinate the work of ASCO staff from CENTRA, the Center for Ethics, Integrity and Law (CEIL), the Department of Finance, and Conquer Cancer® The ASCO Foundation to support the administration of ASCO Research projects. Oversight of the RAU is provided by the ASCO Research Services Committee (RSC), a committee of ASCO Vice Presidents and senior research staff that reviews and manages requests for ASCO data assets, ASCO research projects, and/or requests for biostatistical consultation.

Following initial assessment by the RAU, the ASCO Cancer Research Committee (CRC) will conduct a scientific review according to the criteria listed above and make a recommendation about which ideas merit further development. The CRC leadership may involve additional subject matter experts who are not members of the CRC in this review, as needed. The CRC will prioritize any ideas that merit further development. Ideas that are prioritized will undergo review by the RSC to determine feasibility, and also assess potential funding sources. If the RSC determines that an idea is feasible and potentially fundable, it would look to the CRC leadership to assign (as needed) committee members, subject matter experts, and the respondent who submitted the idea (if they express an interest in being involved and are qualified) to develop the research protocol for final review by the CRC. Any proposals that are outside the Board-approved Scope of ASCO Research but determined meritorious by the review process would require further review by the ASCO Board. The timing of the CRC final review could occur at the Spring 2020 CRC meeting or in a more expedited manner, if required to be responsive to a potential funding opportunity.

A flow diagram depicting the review process is provided below. Projects determined to be of high priority and within the Board-approved scope of research or out-of-scope projects approved individually by the ASCO Board will be supported by the RAU.
Figure 1.

Review and Prioritization of Ideas Submitted to ASCO Request for Research Ideas

- **Research Idea**: Submitted in response to request for ideas
- **Research Admin Unit**: Assess for scope, mission, and principles
- **Cancer Research Committee**: Conduct scientific review and prioritize ideas for further development
- **Research Services Committee**: 1. Screen for feasibility and potential funding 2. With CRC leadership, form working group to develop protocol
- **Cancer Research Committee**: Final review
- **Board Approval Required**: If Out of Scope
- **Launch Project**: Secure Funding

Ongoing Scan for Funding Opportunities: The FPU will regularly scan funding opportunity announcements to identify submission opportunities.
Appendix A: Worksheet for Submission of Ideas for ASCO Research

The ASCO Board is interested in receiving ideas from the membership about high priority research projects that ASCO could conduct. This form provides the guideline for submission of research ideas.

At its March 2019 meeting, the ASCO Board approved the following definition for ASCO Research:

Any project intended to develop generalizable new knowledge that is designed, conducted, or analyzed by ASCO volunteers (as part of the ASCO Volunteer Program) and/or staff on behalf of ASCO or collaboratively between ASCO and other entities.

While each of the headings/sections in the worksheet should typically be used, the individual questions may not all be applicable or need to be answered. Questions serve as a guide to develop the information for each section. If you would like assistance, please contact the ASCO Center for Research and Analytics at ResearchIdeas@asco.org. Respondents should complete submissions using an online response form available at https://redcap.asco.org/surveys/?s=343AALCTHA. Responses are due September 30, 11:59 pm (Eastern).

Name(s):
Member ID#(s):

☐ Prior to submission of this form, I updated my disclosure information at http://coi.asco.org.

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<thead>
<tr>
<th>Project Element Required Fields</th>
<th>Guiding Questions</th>
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<tbody>
<tr>
<td>Name of Project</td>
<td>• Provide a succinct title for the research project.</td>
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<tr>
<td>Background and Rationale</td>
<td>• What is the need or gap that this research project will fill?</td>
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<td></td>
<td>• Note: Responses should generally be 1-3 paragraphs.</td>
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<tr>
<td>Research Objectives/Goals</td>
<td>• What is the overarching goal of this research project?</td>
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<td></td>
<td>• Please describe the research objectives of this project in 2-3 sentences.</td>
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<tr>
<td>Project Description</td>
<td>• What study design would this project use?</td>
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<td>• How would the study be conducted?</td>
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<td>• What type(s) of data would need to be collected or obtained to complete this project? For secondary analysis of existing data, what is the data source that would be used?</td>
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<td>• Note: Responses should generally be 250-500 words or 1 page.</td>
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<tr>
<td>ASCO Mission and Strategic Plan Fit</td>
<td>• How does this project align with ASCO’s mission?</td>
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<tr>
<td></td>
<td>• How does this project align with ASCO’s Strategic Plan?</td>
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<tr>
<td></td>
<td>• Does the project connect to the Research Priorities outlined by ASCO in its 2019 Clinical Cancer Advances report or the ASCO Policy Priorities?</td>
</tr>
</tbody>
</table>

If ASCO decides to launch a project related to this research idea, do you have an interest in being involved in the research project?

☐ Yes
☐ No
Appendix B: ASCO 2019 Research Priorities to Accelerate Progress Against Cancer

Research Priority 1: Identify Strategies That Better Predict Response to Immunotherapies

Description: Cancer immunotherapy encompasses a broad range of medicines and treatment approaches, including vaccines, immune checkpoint inhibitors, and most recently, cellular therapies. These interventions have improved the outlook for multiple cancers, producing long-lasting remissions that can last for years in some patients. At present, however, long-term disease control occurs in just a minority of patients. In addition, immunotherapies can cause substantial adverse effects that can be life-threatening and, in some cases, permanent. Methods to identify patients most likely to benefit from immunotherapy and those at high risk for severe adverse events are urgently needed. The ability to adequately assess benefits and risks of immunotherapy for each individual will lead to better outcomes for patients.

Priority focus areas:
- Identify factors that predict response, long-term disease control, prolonged survival, treatment resistance, and adverse events for all types of immunotherapies
- Develop blood- and tissue-based biomarkers and novel immune-response signatures that predict treatment benefit
- Develop predictive models and algorithms that assign risk of severe immune-related toxicities based on readily available patient data

Research Priority 2: Better Define the Patient Populations That Benefit from Postoperative (Adjuvant) Therapy

Description: A wide range of therapies are recommended to patients after surgery. These therapies, referred to as adjuvant treatments, aim to reduce the risk of recurrence and cancer-related death. Although such therapy has been associated with dramatic improvements in survival for some patients, studies have shown that the risks can outweigh the benefits for others. It is important to ensure that patients who receive adjuvant therapy are the ones most likely to benefit. Eliminating its use in those who do not benefit will be an important step in optimizing care and eliminating unnecessary adverse effects and costs for patients in whom the benefits are unlikely to outweigh the risks.

Priority focus areas:
- Determine factors that identify patients most likely to benefit, or those unlikely to benefit, from adjuvant therapy, including, but not limited to, clinical, pathologic, genomic, biochemical, immunologic, and environmental or social factors
- Develop analytically and clinically valid biomarker tests with proven clinical utility to identify recurrence risk after treatment of the primary tumor and determine the best options for patients with different degrees of risk

Research Priority 3: Translate Innovations in Cellular Therapies to Solid Tumors

Description: Recent FDA approvals of chimeric antigen receptor (CAR) T-cell therapies in leukemia and lymphoma are true milestones in cancer therapy, as signified by ASCO’s 2018 Advance of the Year designation. Although cellular therapies that use a patient’s modified cells to harness the immune system
are transforming care for some patients with blood-based cancers, there are limited data to show whether this strategy can be expanded to patients with solid tumors.

**Priority focus areas:**
- Identify and validate novel antigenic targets uniquely present in solid tumors
- Explore the safety and activity of promising cellular therapies in solid tumors
- Develop strategies that mitigate current challenges in delivering cellular therapies to patients, including exploring the use of cellular products that do not have to be individually manufactured for each patient
- Examine and optimize the cancer care delivery systems needed to safely administer cellular therapies to all who might benefit

**Research Priority 4: Increase Precision Medicine Research and Treatment Approaches in Pediatric Cancers**

**Description:** Genomic tools have been widely deployed for adult patients to characterize common mutations across different types of cancer. In certain cancers, the use of these tools has accelerated development of new targeted therapies that have improved and extended patients’ lives. Despite this success in adult patients, precision medicine treatment approaches have yet to be widely integrated into the treatment of pediatric cancers.

**Priority focus areas:**
- Identify genomic or other molecular alterations in pediatric cancers that can serve as potentially actionable treatment targets
- Develop effective therapeutic agents that can target genomic or other molecular alterations in childhood cancers
- Explore the efficacy of existing targeted therapies in pediatric patients with tumors that have mutations shown to be responsive to medicines that work in adult populations

**Research Priority 5: Optimize Care for Older Adults with Cancer**

**Description:** Although adults age 65 years and older represent the majority of people with cancer, few cancer clinical trials focus specifically on this population. Older patients who do participate in clinical trials are generally not representative of the older patients who oncologists typically see in daily practice. As a result, clinicians face challenges applying clinical trial data to older patients who may have additional health conditions, varying levels of functional ability, and different goals from clinical trial participants. The lack of evidence in this area combined with the inherent diversity of aging populations impedes the delivery of high-quality care for the largest and most rapidly growing segment of patients with cancer.

**Priority focus areas:**
- Develop standardized methods to characterize physiologic aging, such as geriatric assessment and biomarkers of aging, to more reliably predict risk of treatment-related adverse effects in older patients with cancer
- Investigate the impact of cancer treatment on physical function, cognition, and quality-of-life to inform tolerability of cancer therapies in older people
- Investigate the efficacy and toxicity of therapies among older adults most under-represented in clinical trials, such as those with impaired functional status, comorbidities, or frailty
• Conduct clinical trials testing the role of geriatric assessment-guided management to improve outcomes using personalized care; important focus areas include strategies that minimize undertreatment of fit patients and overtreatment of vulnerable or frail patients, supportive care interventions, and care delivery interventions

Research Priority 6: Increase Equitable Access to Cancer Clinical Trials

Description: Certain patient populations are consistently underrepresented in cancer clinical trials. These include patients from racial and ethnic minorities, rural areas, and lower socioeconomic groups and patients older than age 65 years as well as adolescents and young adults age 15 to 39 years. Decreased representation among these groups can limit access to the promising treatments offered through these trials and means that research findings may not fully account for the diversity of biologic, social, and cultural factors that influence outcomes. Additional research is needed to ensure that every patient with cancer, regardless of race, ethnicity, age, geographic location, or socioeconomic status, benefits from research advances.

Priority focus areas:
• Improve understanding of the barriers to trial enrollment among various under-represented groups, taking into consideration patient, practice, community, and trial-specific factors
• Develop and test interventions that enhance clinical trial enrollment among under-represented populations (examples may include use of educational tools, telehealth, and community-based involvement and participatory research)
• Evaluate novel strategies to improve access to clinical research resources in areas with large proportions of under-represented minorities
• Develop mechanisms that improve awareness and education about clinical trials among under-represented groups and the physicians treating them
• Investigate differences in cancer incidence, prevalence, natural history of disease, and treatment experience, including efficacy and toxicity, among under-represented populations

Research Priority 7: Reduce the Long-Term Consequences of Cancer Treatment

Description: Advances in cancer treatment have resulted in a record number of cancer survivors—more than 15.5 million. Although this is a tremendous accomplishment, survivors still face long-term consequences of cancer, including adverse effects of cancer therapies that affect quality of life. These adverse effects, which commonly include peripheral neuropathy, cognitive impairment, and cardiotoxicity, pose a substantial burden not only to patients but also to the health care system.

Priority focus areas:
• Identify genetic variants associated with increased risk of treatment-related toxicities
• Deepen understanding of the underlying mechanisms of toxicities from targeted treatments, determine their contribution to long-term effects, and develop novel strategies to mitigate or eliminate such toxicities
• Develop new tools to facilitate long-term tracking of patient outcomes that include patient-reported outcome measures
Research Priority 8: Reduce Obesity’s Impact on Cancer Incidence and Outcomes

**Description:** The incidence of obesity has dramatically increased over the past several decades. Despite being the second leading preventable cause of cancer, a recent ASCO survey found that only 35% of Americans recognize excess body weight as a cancer risk factor. Obesity is associated with poorer cancer survival and can contribute to increased risk of treatment-related adverse effects. If current trends continue over the next 20 years, it is estimated that obesity will lead to more than 500,000 additional cases of cancer each year in the United States and will surpass smoking as the leading preventable cause of cancer.

**Priority focus areas:**
- Improve the understanding of the mechanisms through which weight and energy balance, including physical activity and dietary factors, contribute to cancer development and progression
- Investigate how obesity affects response to therapy, risk of cancer recurrence, and long-term cancer outcomes
- Assess the impact of energy balance interventions, such as weight loss, increased physical activity, and improved dietary quality, on cancer risk, recurrence, and mortality
- Identify effective interventions that optimize energy balance in people at risk and who are living with cancer

Research Priority 9: Identify Strategies to Detect and Treat Premalignant Lesions

**Description:** Many cancers begin as high-risk lesions that invariably progress to invasive cancer. Currently, little is known about the genetic makeup, heterogeneity, microenvironment, and what causes some of these lesions to progress to invasive cancer. Increased knowledge will help guide new approaches to intercept and eradicate high-risk lesions before their transformation to malignancy.

**Priority focus areas:**
- Identify specific molecular pathways that drive progression of preinvasive lesions to invasive cancer and develop interventions that can delay or prevent progression to malignancy
- Identify features of the microenvironment of premalignant lesions that are associated with progression to invasive disease
- Investigate novel methods for evaluation of premalignant lesions to better inform the risk or likelihood of progression to invasive disease
Appendix C: ASCO 2019 Policy Priorities

ASCO’s Government Relations Committee establishes policy priorities on an annual basis (www.asco.org/advocacy-policy/policies-positions-guidance/policy-priorities). These priorities are updated as needed to reflect emerging issues. ASCO develops and evaluates policy topics in an evidence-based way, including generating evidence where none exists.

Policy Priority 1: Pursue access to high quality, affordable care for every patient with cancer

- Advocate for policies at the federal and state level to ensure that all cancer patients and survivors have access to adequate and affordable health insurance.

- Advocate for policies that require Medicare, Medicaid, Health Insurance Exchanges, and commercial health plans to provide coverage for the full range of services needed to prevent, diagnose and treat cancer.

- Advocate for policies that protect cancer patients from high cost-sharing requirements that target anti-cancer medicines and supportive care therapies.

- Ensure continuation of clinical trials coverage provisions and extend these to all health plans for all phases of clinical trials.

Policy Priority 2: Advance evidence-based policies and delivery system reform that supports oncology providers in their delivery of high quality, high value cancer care

- Support continuity of patient access to anti-cancer therapies by maintaining the current ASP system until an adequate value-based replacement is tested and adopted.

- Advocate for payment models that include payment supporting the full range of services needed by patients with cancer, including multidisciplinary care coordination, patient counseling and navigation, palliative care, tobacco cessation, survivorship care, and end of life care.

- Pursue qualification of PCOP as an alternative payment model under Medicare Access and CHIP Reauthorization Act (MACRA). Advocate for the testing and adoption of a variety of oncology specific Alternative Payment Models (APMs) and models that contain components that are compatible with the field of oncology.

- Ensure MACRA implementation supports an effective, efficient and healthy practice environment. This includes establishing measures that ensure fair and accurate provider performance assessment, addressing the potentially negative impacts of including Part B drugs in assessing resource utilization performance, and allowing practices to use QOPI to fulfill federal performance reporting requirements.
• Promote policies that eliminate the obligation for practices to participate in multiple pathway and reporting systems.

• Promote the exchange of health care information to advance treatment and support delivery of high value, high quality care by removing barriers to, advancing the awareness of and increasing support for learning systems like ASCO’s CancerLinQ and by pursuing regulatory and legislative remedies to information blocking.

• Advocate for Congress to require the CDC, other collaborating institutions, and states to develop comprehensive cancer control plans that include consideration of survivorship care, and promoting the implementation, evaluation, and refinement of existing cancer control plans.

Policy Priority 3: Advocate for policies that support a robust federally funded cancer research, prevention, drug development, and clinical trials system.

• Advocate for robust and sustainable increases in federal budgets for the National Institutes of Health (NIH) and advocate for funding for the Cancer Moonshot Initiative.

• Advocate for funding of more inclusive and robust clinical trials, specifically including minorities and the underserved.

• Advocate for policies that support a sustainable clinical trials system, including standardization and streamlining of administrative and regulatory processes associated with clinical trials, as well as reimbursement for the additional time and effort required for clinical investigators to involve patients in clinical trials.

• Advocate for increased funding and Congressional support for FDA programs to review safety and efficacy of therapies and diagnostics, drug shortage prevention programs, and regulatory authority of tobacco products.