



ASCO-ACCC REQUEST FOR IDEAS (RFI): NOVEL STRATEGIES AND PRACTICAL SOLUTIONS TO INCREASE PARTICIPATION OF RACIAL AND ETHNIC MINORITY POPULATIONS IN CANCER TREATMENT TRIALS

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Inquiries, questions, and requests for clarification related to this request can be emailed to:

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or

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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.cancerlinq.org, explore patient education resources at www.Cancer.Net, and follow us on [Facebook](#), [Twitter](#), [LinkedIn](#), and [YouTube](#).

2. ACCC Overview

The Association of Community Cancer Centers (ACCC) is the leading education and advocacy organization for the cancer care community. Founded in 1974, ACCC is a powerful network of 25,000 multidisciplinary practitioners from 2,100 hospitals and practices nationwide. As advances in cancer screening and diagnosis, treatment options, and care delivery models continue to evolve—so has ACCC—adapting its resources to meet the changing needs of the entire oncology care team. For more information, visit acc-cancer.org and follow us on [Facebook](#), [Twitter](#), [LinkedIn](#), and [Instagram](#); read our blog, [ACCCBuzz](#); and tune in to our podcast, [CANCER BUZZ](#).

3. Background: Participation of Racial and Ethnic Minority Populations in Cancer Treatment Trials

Despite the importance of diversifying clinical trial participants, minority populations continue to be particularly under-represented in cancer treatment trials when compared with their percentages in the overall population of patients with cancer (Murthy 2004, Chen 2014). Recent analyses of cancer therapeutic trials found that only 4% to 6% of trial participants are Black and 3% to 6% are Hispanic, despite representing 15% and 13% of all patients with cancer, respectively (Loree et al 2019, Duma et al 2018).

A recent review of 1,012 cancer therapeutic trials listed on ClinicalTrials.gov between 2003 and 2016 found that only 31% of the trials reported on participant race/ethnicity. Patients who were Black or Hispanic were reportedly less likely to enroll in cancer treatment trials than patients who were non-Hispanic white and there was a decrease in participation by patients who were Black or Hispanic since 2003, suggesting that the strategies implemented to recruit minorities to have not been effective.

There are a variety of reasons for the lack of diversity in trial participants, including provider bias in patients to approach and challenges with cultural competency; narrow eligibility criteria and other study design barriers; challenges with access, insurance coverage, and cost of care; awareness about trials; a lack of trust in the healthcare system and/or clinical research; linguistic, cultural or literacy-related barriers; and factors such as family and community engagement (Adams-Campbell 2004, Wynia 2006, Nipp 2015, Unger 2016 and 2019, Ford 2008). Under-representation results not only from failure to enroll patients in trials but also from a lack of retention of minority populations while on study (Arnold 2014).

4. Opportunity to Submit Ideas

ASCO and ACCC are committed to working with our members to ensure that cancer treatment trials fully reflect the diversity of people at-risk for or living with cancer. Our organizations are collaborating on an initiative to first identify and then implement ideas to increase cancer treatment trial participation of racial and ethnic minority populations.

As part of the initiative, ASCO and ACCC are issuing this Request for Ideas (RFI) to solicit novel strategies and practical solutions from the cancer community to increase participation in cancer treatment trials with a particular focus on under-represented patients from racial and ethnic minority populations.

Priority idea submissions should address barriers to participation in cancer treatment trials for patients from under-represented racial and ethnic minority patient populations and focus on high-priority, novel strategies and practical solutions that address those barriers. Ideas that are identified and selected through this RFI will be evaluated by the ASCO-ACCC Steering Group (ASCO-ACCC SG) and may be modified, combined, and implemented through appropriate organizational mechanisms, including the ASCO Targeted Agent and Profiling Utilization Registry ([TAPUR™](#)) Study (see Section 9 of this RFI for more information).

5. Important Information for Respondents

- This request for novel strategies and practical solutions is not intended to convey an offer or a commitment by ASCO and/or ACCC to undertake development, implementation, and/or evaluation of a specific idea or of any idea. ASCO and/or ACCC decisions are dependent, in part, on availability of funding outside of respective organization budgets and/or other resources necessary to conduct the project.
- This request for ideas does not indicate an intent on the part of ASCO or ACCC to provide funding for ASCO or ACCC projects.
- If a submitted idea is selected for development, implementation, and/or evaluation, the submitter will have the opportunity to indicate an interest in participating as part of the project team.
- Responses that present pragmatic approaches to improving cancer treatment trial enrollment and advance the respective missions of each organization will be prioritized, provided that sufficient external resources are secured, and staff resources are available.
- As a condition of submission in response to this request, the respondent represents that the information and ideas contained are freely given to ASCO and ACCC, and that the respondent has the authority to share this idea for consideration of planning and execution by ASCO and/or ACCC, with or without participation of the respondent.

6. Examples of Novel Strategies and Practical Solutions

Strategies and solutions may include tools and resources such as site self-assessments and educational resources (e.g., for cultural competency geared toward mitigating bias), and culturally appropriate patient education and outreach engagement strategies that raise awareness about the benefits of cancer treatment trial participation. Applications are not limited to the referenced strategies although strategies that have a track record of success will be prioritized. All promising ideas that address practical approaches to increasing participation of under-represented racial and ethnic minority populations in cancer treatment trials will be considered. Specific examples include:

- Duke Cancer Institute, Durham, N.C., implemented a health disparities and equity cancer program with initiatives like the *Community Health Ambassador Program*, the *“Just Ask” Minority Participation in Research Program*, and the *Diversity and Inclusion in Patient Care and the Workplace Program*.
- Yuma Regional Medical Center Cancer, Yuma, Arizona, leveraged traditional Hispanic *promotoras* and community health workers to educate and improve the care of a rural, migrant, and multicultural patient population, including many undocumented patients.
- Benefis Sletten Cancer Institute, Great Falls, Montana, which treats patients from three American Indian reservations and one federally recognized landless tribe, opened a Native American Welcoming Center and developed culturally sensitive programs and services, such as a smudging ceremony, where a cleaning smoke bath is created and used to purify the body, aura, and energy.
- Mary Bird Perkins Cancer Center, Baton Rouge, improved early detection of cancer for its medically underserved patients, many of whom are Black American, through development of culturally appropriate practices that eliminated barriers to care, data-driven tools that monitor health outcomes by zip code, and strategic partnerships that maximize patient transitions throughout the care continuum.

Read more about these and other novel strategies and practical solutions in practice at ACCC member programs in Appendix B.

7. Guiding Principles

ASCO and ACCC agree that high priority ideas should adhere to the following principles.

- Pursue novel strategies and practical solutions that ASCO and/or ACCC are uniquely poised to address
- Increase opportunity to participate in cancer treatment trials by removing barriers
- Inform ASCO and/or ACCC policy and/or resource development to increase participation of under-represented minority populations in cancer treatment trials
- Employ methods and tools that follow ethical standards and promote equity and could be used by the broader oncology community
- Engage patients and communities in all aspects of the cancer treatment trial process
- Increase acceptance of cancer treatment trials through development of culturally sensitive processes and education materials

8. Review and Prioritization

ASCO and ACCC will use the following criteria to review and prioritize proposed ideas.

- Quality of the novel strategy or practical solution
- Potential to address barriers to racial and ethnic participation in cancer treatment trials
- Potential replicability, as well as ability to disseminate and implement
- Feasibility of the project, including methodologies/approach, timelines, resources, funding and preliminary evidence of success
- Indications that the submitter is a program champion and has a demonstrated commitment to quality and equitable cancer care and to addressing racial and ethnic disparities in clinical trials

ASCO and ACCC are using a single portal for submission of responses to this RFI:

https://redcap.link/ASCO_ACCC_RFI. (Note: A link to Frequently Asked Questions (FAQ) is provided within the REDCap submission form.)

The ASCO-ACCC SG will review and may select ideas for modification and implementation. All respondents will be notified as to the decision of the SG related to their submission. ASCO and ACCC may choose to pursue ideas in collaboration between the two organizations or the organizations may choose to develop ideas independently.

9. Resource for Respondents' Consideration

The Targeted Agent and Profiling Utilization Registry (TAPUR™) Study Overview

The TAPUR Study is a phase II basket study that evaluates anti-tumor activity of commercially available targeted agents in patients with advanced cancers with specific genomic alterations. TAPUR offers a clinical trial opportunity for research collaborators to learn about the performance of specific targeted anti-cancer therapies in real-world patients. Eight pharmaceutical companies are collaborating with ASCO in this precision medicine phase II basket trial.

The TAPUR Study is open at more than 110 clinical sites across the U.S. and enrolling patients with advanced solid tumors for which standard treatment options are no longer available. **NCT#02693535 (For more information on TAPUR, please visit: <https://www.tapur.org/>)**

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- [Strategies Addressing Barriers to Clinical Trial Enrollment of Underrepresented Populations: A Systematic review](#) (Heller et al, 2014, PMID:25131812)
- [Barriers and Facilitators to Participation of Minorities in Clinical Trials](#) (Schmotzer, 2012, PMID: 22764647)
- [Recruiting Minorities Where They Receive Care: Institutional Barriers to Cancer Clinical Trials Recruitment in Safety-net Hospitals](#) (Joseph et al, 2009, PMID: 19580887)
- Involving Minority and Underrepresented Women in Clinical Trials: The National Centers of Excellence in Women's Health (Killien 2014, PMID: 11153102)

Appendix A:

Worksheet for Submission of Novel Strategies and Practical Solutions to Increase Participation of Racial and Ethnic Minority Populations in Cancer Treatment Trials

The link to the submission form is: [https://redcap.link/ASCO ACCC RFI](https://redcap.link/ASCO_ACCC_RFI)

The American Society of Clinical Oncology (ASCO) and Association of Community Cancer Centers (ACCC) Steering Group (SG) is interested in receiving ideas from their membership about novel strategies and practical solutions that address barriers to participation of racial and ethnic minority populations in cancer treatment trials. The ideas will inform initiatives developed through the ASCO-ACCC SG. This form provides a guide to help develop ideas for submission.

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. Probes are offered for some questions to guide you as you develop content.

If you would like assistance, please contact ASCO at ResearchIdeas@ASCO.org.

This RFI will remain open until August 24th, 2020 at 11:59 pm (Eastern).

Name(s) (first, last):

Organization:

Email:

Please indicate if you (or someone in your group) is an ASCO and/or ACCC member:

Required Fields	Guiding Questions
Title of Strategy or Solution	<ul style="list-style-type: none"> Provide a succinct title for the submission.
Background and Rationale	<ul style="list-style-type: none"> What is the barrier that this novel strategy or practical solution will address? <p>Note: Responses should generally be 2-3 sentences.</p>
Objectives/Goals	<ul style="list-style-type: none"> What is the overarching goal of this novel strategy or practical solution? How will the strategy increase participation of racial and ethnic minority populations in cancer treatment trials? Is the submitted strategy or solution an original idea or adapted from another innovative strategy or practical solution? (Please clarify) <p>Please describe the objectives of this strategy in 2-3 sentences.</p>
Description	<ul style="list-style-type: none"> Are there specific type(s) of data that would need to be collected or obtained to evaluate this novel strategy or practical solution? Are there preliminary results data available associated with use of this idea? (If so, please summarize) Does the novel strategy or practical solution include a tool for testing in this submission? (If so, please upload) <p>Note: Responses should generally be 250-500 words or 1 page.</p>

If ASCO and/or ACCC decides to launch a project related to this novel strategy or practical solution, do you have an interest in being involved?

- Yes
- No

Appendix B. Novel Strategies and Practical Solutions in Practice at ACCC Member Programs

1. In 2016 Duke Cancer Institute won an [ACCC Innovator Award](#) for its health disparities and equity cancer program and its five-step roadmap for conducting health assessments that aimed to reduce cancer disparities and improve population health through community partnerships. Components included 1) an engaged and diverse community advisory council; 2) robust and collaborative health assessments; programs, services, and research priorities; 3) aligned partnership programming; and 4) programmatic evaluations and outcome measures. To improve equity in cancer care, specific programs were developed including:
 - **A Community Health Ambassador Program.** This collaborative and interactive cancer and clinical trials training program reaches out to diverse members of the community, including faith organizations. Ambassadors are selected by faith or community leaders to be trained at a one-day, six-hour course that educates participants about cancer risk factors, symptoms, screenings, and the psychological effects of cancer. Upon completion, Ambassadors are equipped with knowledge and tools to implement cancer awareness activities within their own organizations. Ambassadors are directly connected to Duke Cancer Institute patient navigators, who serve as a resource and a link to the healthcare system for those needing cancer screening or other services.
 - **The “Just Ask” Minority Participation in Research Program.** To ensure patients are aware and knowledgeable about research and clinical trial participation and that researchers are well equipped with the necessary skills to communicate with diverse populations, the “Just Ask” program provides individual and group consulting support to research teams and clinical staff to improve minority enrollment in research. Health communications and cultural competency training is also provided, as well as interventions to recruit and retain minorities in research were developed.
 - **The Diversity and Inclusion in Patient Care and the Workplace Program** provides training and education to faculty and staff around bias, diversity, and inclusion. Training segments vary and are tailored to specific audiences and include topics like understanding and valuing diversity, power, and privilege, patient and community engagement, hiring from a diverse pool of candidates, and assessing our own comfort and discomfort with “difference.”

2. Yuma Regional Medical Center Cancer, Yuma, Arizona, has a large rural, migrant, and multicultural patient population, including many undocumented patients. To meet the needs of these at-risk patients, Yuma [hired a community health worker to work in tandem with traditional Hispanic promotoras](#). (*Promortoras* are often females and trusted family or friends of a patient. While not trained in healthcare, these individuals understand how to maneuver through the healthcare system, and they can speak Spanish.) Among other responsibilities, the community health worker developed collaborating partnerships with organizations such as *Campesinos Sin Fronteras*, which partners with low-income migrant workers, the agriculture community, and other vulnerable patient populations in Yuma County to prevent chronic disease and other illnesses. Another partnering organization was the Regional Center for Border Health and its Well Woman Program, which receives federal and state funding to provide breast and cervical cancer screenings to the community. After developing easy-to-understand referral and tracking forms and culturally relevant marketing resources in two languages, this community health worker went out into towns and neighborhoods to meet patients where they live and work. Outcomes included: 5,800 families reached through community outreach

activities; 4,472 people reached through educational sessions; 1,825 families reached through door-to-door community health worker visits; and education and outreach provided in 9 different towns.

3. In Great Falls, Montana, [Benefis Sletten Cancer Institute's](#) service area includes three American Indian reservations and one federally recognized landless tribe. The Native American population makes up about 7 percent of the institute's patient population. To meet these patients' cultural needs, the health system built a Native American Welcoming Center located near the front entrance of the main hospital, just two blocks from the cancer institute. This unique space is available to Native American patients and their families, a place where they can gather together and participate in various cultural practices, such as a smudging ceremony, where a cleaning smoke bath is created and used to purify the body, aura, and energy. A clinical trial team, which consists of a clinical regulatory research coordinator, a clinical research registered nurse, and a part-time clinical research nurse, screens all new patient referrals and those whose cancers recur for potential clinical trial options. Benefis Sletten Institute also works with the Montana Cancer Consortium to give patients access to a broad range of national clinical trials. About 4 percent of the institute's patients are enrolled in clinical trials annually, and the program has between 80 and 120 trials open for enrollment, which are either nationally sponsored or offered by industry.

4. In 2016 Mary Bird Perkins Cancer Center, Baton Rouge, won an [ACCC Innovator Award](#) for its work to improve early detection of cancer for the medically underserved who often face access challenges due to insurance status, limited availability of PCPs, low literacy rates, and/or other barriers. Since 2002, Mary Bird Perkins Cancer Center has operated two year-round, mobile medical clinics that provide free screenings for multiple cancer types with follow-up on abnormal findings by patient navigators. Culturally appropriate practices eliminate barriers to care, data-driven tools monitor health outcomes by zip code, and strategic partnerships maximize patient transitions throughout the care continuum. Mary Bird Perkins evaluated programmatic effectiveness and success by answering five key questions: 1) Are we using evidence-based best practices for cancer screening and outreach to medically underserved adults, 2) Are we reaching the targeted population, 3) Are we effective in increasing screening rates and compliance, as well as reducing late-stage diagnosis among the underserved, 4) Is our approach cost effective, and 5.) Does the program ensure timely follow-up of abnormal findings to transition participants quickly into treatment, if diagnosed?

5. Mary Bird Perkins was also one of the cancer programs involved in efforts to [reduce cancer healthcare disparities as part of the NCCCP program](#). Other ACCC member programs that participated as an NCCCP site included Sanford USD Medical Center, Spartanburg Regional Hospital, St. Joseph Hospital/Orange, Christiana Care Healthcare System, and St. Joseph's/ Candler. These NCCP sites identified community outreach and screening events as critical to successfully engaging disparate communities for reducing cancer disparities. To that end, NCCCP sites developed an intentional and bi-directional process to build relationships in the community and worked to develop tools and resources designed to improve, expand, and demonstrate the impact of outreach efforts. NCCP sites shared best practices and tools, including 1) cultural awareness webinars to provide education on how disparate populations' healthcare beliefs may influence interactions with the healthcare team, 2) case studies to share strategies for reaching underserved populations and to help identify promising practices, as well as challenges, related to increasing enrollment in clinical trials, 3) a

template for community outreach to guide outreach program planning with an overview of important considerations for how to develop, implement, and evaluate focused community outreach efforts.

6. These [NCCP sites also used patient navigation](#) to help reduce cancer disparities. For example, St. Joseph Hospital of Orange, Calif., developed a navigation program that was culturally tailored for Native Hawaiian and Pacific Islanders. Another NCCCP site specifically identified rural areas and American Indians as target populations and hired a regional navigator to focus on challenges unique to the specific communities. The regional navigator traveled throughout rural communities and area reservations to meet with key staff members at healthcare programs. One goal of these meetings was to identify existing supportive programs so that cancer patients could enroll in them in their home communities. Free educational programs, such as the Cancer 101 series available through NCI's Spirit of Eagles program, were used to stress the importance of screening. This site's experience highlighted the importance of conducting fact-finding and trust building endeavors before developing a program. A third NCCP site focused to focus on the Black American community, starting with HPV vaccinations. Once partnerships were formed, the site initiated a health fair event for OB/GYN adolescents. Part of the goal was to offer cervical cancer screenings to parents and/or guardians of the targeted girls in this patient population.

7. A five-year NCI cancer disparities grant (part of NCI's Cancer Disparities Research Partnership, a federal program to reduce cancer mortality among minorities) awarded to Rapid City Regional Hospital, Rapid City, S.D., funded development of the [Walking Forward](#) program to look to increase cancer survival rates among American Indians in western South Dakota and the Northern Plains. Program components included clinical trials, patient navigation, a genetic study, community outreach and education, and administration of a 1,000-participant community survey. Culturally trained navigators met with patients and families to discuss options and assist with decision making by educating patients and families about the implications of different treatment options. Because community members serving as *Iyeska* (translators) and *Eyapaha* (advocates) were respected and recognized as having a valued role in Lakota/Dakota/Nakota cultures these individuals were included as part of shared decision making.