



Friends of Cancer Research and ASCO Applaud NCI's Expansion of Clinical Trial Eligibility Criteria

WASHINGTON, DC - The American Society of Clinical Oncology, Inc. (ASCO) and Friends of Cancer Research (*Friends*) applaud the National Cancer Institute's (NCI) recent revision of its [clinical trial protocol template](#) to [broaden eligibility criteria](#) for cancer clinical trials. The protocol template was expanded to help increase the opportunity for participation in NCI-funded clinical trials for patients with certain health care conditions, as well as to provide an opportunity for patients younger than age 18 to participate in adult clinical trials in certain circumstances.

"By expanding its clinical trial eligibility requirements, NCI is helping to ensure that participants in clinical trials better reflect the patients who will eventually receive cancer therapies once they're applied in routine clinical care," said ASCO President Monica M. Bertagnolli, MD, FACS, FASCO.

"These requirements balance patient safety with the need to make sure that clinical trial results are generalizable to the broader patient population."

NCI issued a guidance document for researchers to use in future clinical protocols that includes more expansive eligibility criteria for patients with pre-existing conditions in the following areas: brain metastases, HIV/AIDS, chronic hepatitis B, history of hepatitis C, organ dysfunction (specifically related to liver, kidney, and heart dysfunction), and prior and concurrent malignancies. The protocol template also removed barriers to clinical trial participation for patients under the age of 18. New protocols submitted to NCI's Cancer Therapy Evaluation Program (CTEP) on or after November 1, 2018, will be expected to use these eligibility requirements.

"We commend NCI for their recent effort to expand clinical trial eligibility criteria based on the recommendations put forth by *Friends* and ASCO earlier this year," said Jeff Allen, PhD, President and CEO, Friends of Cancer Research. "Expanding access to clinical trials is crucial for patients, particularly those that historically have been excluded. We applaud NCI's efforts to encourage the inclusion of more patients."

"NCI is extremely supportive of broadening eligibility criteria to make clinical trials more representative," said Jeff Abrams, MD, Associate Director of the Cancer Therapy Evaluation Program, NCI. "The goal is to expand access to clinical trials and remove previous barriers for patients with pre-existing conditions and we thank all those that participated in this important effort to expand access."

ASCO and *Friends* suggested revisions to the NCI protocol template based on ASCO and *Friends*' recommendations to the scientific community developed by groups of experts and [published](#) in a Journal of Clinical Oncology special series in October 2017. The experts—including leaders from the NCI National Clinical Trials Network and NCI staff, as well as drug/biotech manufacturers, investigators, patient advocates, and regulators—divided into working groups that developed consensus recommendations for eligibility criteria in these five areas. ASCO and *Friends* have been working since publication of the recommendations to implement them in a variety of settings. In addition to the NCI protocol template, ASCO and *Friends* [proposed guidance documents to the U.S. Food and Drug Administration](#) (FDA) and have presented the recommendations to cancer researchers at several national meetings.

Eligibility criteria are the specifications that patients must meet in order to participate in clinical trials and often include age, current health status, medical history, and particular type of cancer and its stage. Researchers define their study populations using such characteristics to minimize the impact of variables that could confound interpretation of the study results. However, more stringent eligibility criteria mean fewer patients qualify to participate in trials, potentially making the results less applicable to treatment of the more diverse patient populations seen in clinical practice.

ASCO and *Friends* began their collaborative effort to update eligibility criteria in 2016 to promote greater patient participation in cancer clinical trials, working closely with the FDA. They identified the five areas that are now part of NCI's updated protocol template where eligibility criteria were most likely to restrict a patient's participation in a trial but least likely to affect the safety of participants: brain metastases, HIV/AIDS, minimum age, organ dysfunction, and prior and concurrent malignancies.

[View the new Cancer Therapy Evaluation Program protocol templates, guidelines, and updated language on eligibility criteria.](#)

About Friends of Cancer Research

Friends of Cancer Research drives collaboration among partners from every healthcare sector to

power advances in science, policy and regulation that speed lifesaving treatments to patients. For more information, please visit www.focr.org or on [Twitter](#).

About ASCO

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 nearly 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's Conquer Cancer Foundation supports the Society by funding groundbreaking research and education across cancer's full continuum. Learn more at www.ASCO.org, explore patient education resources at www.Cancer.Net, and follow us on [Facebook](#), [Twitter](#), [LinkedIn](#), and [YouTube](#).