



Health Equity Application Toolkit

Stand Up To Cancer is committed to lowering the barriers of access to new treatments to all cancer patients. In doing so, with mounting evidence for the need to develop precision medical treatment and intervention solutions to serve diverse patient populations, we are actively engaged in changing the health equities landscape by supporting expanding diversity with the inclusion of historically underrepresented racial and ethnic minority populations into clinical trials that we fund. We are especially interested in supporting clinical trials and research studies that have developed successful strategies, measurable outcomes, and robust outreach plans to feasibly and effectively include these populations into these studies.

As one of the leading funders of cancer research, we believe it is our duty to ensure that minority representation in cancer clinical trials is addressed. Now, more than ever, better understanding of the role of biology in cancer treatment, advances in precision treatment, and development of new technologies demands that we also make significant improvements in diverse clinical trial participation to ensure that all communities have equal access to potentially life-saving treatments

SU2C's Committee for Health Equity in Cancer Clinical Trials in collaboration with SU2C scientific leadership, developed procurement language that now requires applicants for funding to include three critical components related to health equity:

- an indication of whether the research will address the populations expected to benefit from widespread use of newly developed treatments;
- patient recruitment and retention plans for including historically underrepresented racial and ethnic populations – such as the need for additional trial sites or mechanisms to reduce barriers to access; and
- a letter of support from the lead institution's Chief Diversity Officer, or an equivalent position.

This Toolkit is intended to provide additional resources and topics for consideration as you formulate an application. Please refer to the application materials for specific requirements of the grant.

Recommendations to Increase Diverse Enrollment in Cancer Clinical Trials

- **Patient Engagement Practices** - A provider's recommendation is the most important factor that influences a patients' willingness to participate in clinical research. The provider is ultimately responsible for discussing with the patient their potential eligibility for a specific clinical trial at the time patients make decisions on treatment as part of holistic discussions on the current standard of care and the most appropriate treatment approach. Three additional notable practices are:
 - Engage the patient in trial participation decision making; ensure the availability of culturally appropriate, ethnicity-specific, and cognitively empowering materials; and earning the trust of the patient.
 - Provide culturally and linguistically accessible study materials. For patients to make an informed decision regarding the choice to participate in clinical research, study materials (for example, educational pamphlets) must be both culturally and linguistically accessible and user friendly. This includes information produced in various formats (for example, print, audio, or video) and in common and lesser-known languages of ethnic communities.
 - Build Trust. Patients are more likely to engage in clinical research if providers and researchers take the time to build trusting relationships with patients and their families.
- **Strategies Used by Multiple Institutions to Enhance Community Outreach and Engagement** -
 - Offer cultural competence training for staff that includes information about motivators, challenges, and barriers to research participation among racial and ethnic minorities.
 - Create community advisory boards composed of diverse stakeholders to guide the development, feasibility, and implementation of research studies.
 - Engage lay community representatives—ambassadors—from diverse communities to cultivate community talent and tap into their expertise and networks to reach potential research participants.
 - Be transparent. Transparency in sharing research findings, potentially via concise, plain language summaries to help participants understand their contributions to science and their community.
- **Practices in support of recruitment and retention of Racial and Ethnic Minorities Groups**
 - Identify new trial sites during the selection process to understand their approach and capabilities, asking active investigator sites to recruit a diverse patient cohort and provide their recruitment strategy.
 - Consider protocol inclusions and exclusions, such as non-clinically relevant criteria that disproportionately affect minorities.
 - Discuss prospective support/logistics measures for patients so that they understand what is available in the recruiting stage.
 - Provide, during investigator meetings, a rationale for the inclusion of minorities and provide sites that are culturally sensitive and health literate recruitment materials for use by research staff.
 - Engage industry-supported patient engagement programs of representative populations of patients and care partners for insights into protocol and feasibility designs.

- Work with patient organizations to share and educate membership about the availability of specific clinical studies.

More Information on Approaches to Equitable Enrollment Practices

NCI Health Disparities Resources: <https://www.cancer.gov/about-nci/organization/crchd/about-health-disparities/resources>

FDA Guidance: Enhancing the Diversity of Clinical Trial Populations — Eligibility Criteria, Enrollment Practices, and Trial Designs Guidance for Industry. <https://www.fda.gov/media/127712/download>

FDA Guidance: Collection of Race and Ethnicity Data in Clinical Trials
<https://www.fda.gov/media/75453/download>

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Harvey, D.R., Rubinstein, W.S., Ison, G., *et al.* Impact of broadening clinical trial eligibility criteria for advanced non-small cell lung cancer patients: Real-world analysis. *Journal of Clinical Oncology* 2019 37:18_suppl, LBA108-LBA108 https://ascopubs.org/doi/abs/10.1200/JCO.2019.37.18_suppl.LBA108

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Vuong, I., Wright, J., Nolan, M.B. *et al.* Overcoming Barriers: Evidence-Based Strategies to Increase Enrollment of Underrepresented Populations in Cancer Therapeutic Clinical Trials—a Narrative Review. *J Canc Educ* (2019). <https://doi.org/10.1007/s13187-019-01650-y>

Haggerty, J., Chin, M., Katz, A., *et al.* Proactive Strategies to Address Health Equity and Disparities: Recommendations from a Bi-National Symposium; *The Journal of the American Board of Family Medicine* May 2018, 31 (3) 479-483; DOI: 10.3122/jabfm.2018.03.170299

Van Meter, K. C., Christiansen, L. E., Hertz-Picciotto, I., Azari, R., & Carpenter, T. E. (2008). A procedure to characterize geographic distributions of rare disorders in cohorts. *International journal of health geographics*, 7, 26. <https://doi.org/10.1186/1476-072X-7-26>

NCI Center to Reduce Cancer Health Disparities (CRCHD): <https://www.cancer.gov/about-nci/organization/crchd>

FDA Office of Minority Health and Health Equity: <https://www.fda.gov/consumers/minority-health-and-health-equity/racial-and-ethnic-minorities-clinical-trials>

SU2C Resources

SU2C Research and Clinical Trial Finder: https://standuptocancer.org/research-finder/?type=research_project&grant_type=Convergence_Team&orderby=date&order=DESC¤t_page=1

CulturIntel Infographic on Insights and Barriers Towards Cancer Clinical Trials
https://drive.google.com/file/d/1oud4wl9u75Y5KHU6yOAFy_hEztwWpPA3/view?usp=sharing

Community and Advocacy Organizations

NCI Center To Reduce Cancer Health Disparities: <https://www.cancer.gov/about-nci/organization/crhd/about-health-disparities>

FDA Office of Minority Health and Health Equity: <https://www.fda.gov/consumers/minority-health-and-health-equity/racial-and-ethnic-minorities-clinical-trials>

Patient Focused Materials

SU2C Clinical Trials Toolkit, Including Animated Videos on Topics Pertaining to Clinical Trials (English and Spanish): <https://thesocialpresskit.com/Clinical-Trials>

SU2C For Patient and Caregivers webpage: <https://standuptocancer.org/for-patients-and-caregivers/clinical-trials/>

FDA's Office of Minority Health Clinical Trial Diversity Stakeholder Communications Toolkit:
<https://www.fda.gov/media/98497/download>

Conversations on Covid-19: Impacts in Communities of Color
<https://www.nationalacademies.org/resource/conversations-on-covid-19-impacts-on-communities-of-color>