Key terms for these Notice of Funding Opportunities (NOFOs):

<u>Health Equity</u>: Achieving health equity requires ongoing societal efforts to address avoidable inequalities, historical and contemporary injustices, the elimination of health and healthcare disparities, and valuing everyone equally. Cancer control equity is defined as everyone having a fair and just opportunity to prevent, detect, receive quality care for, and survive cancer with optimal quality of life. Health equity is not only the goal or outcome, but is also the approach, process, and methods by which the research is conducted.

Social Determinants of Health (SDOH): The unfair and avoidable factors in health status that drive health inequities. SDOH are conditions in the environment where people are born, grow, live, learn, work, play, and age that impact health outcomes. These circumstances are shaped by the distribution of money, power, and resources at global, national, and local levels, which are themselves influenced by policy choices. Examples of SDOH that have the potential to adversely affect health include housing instability, transportation barriers, structural racism and discrimination, language accessibility and health literacy, food access and insecurity, limited physical activity opportunities, as well as poor air and water quality. SDOH can be positive or negative but may create the adverse conditions that result in poor health, known as social risks.

<u>Multilevel Intervention</u>: Intervention(s) occurring at least at two levels simultaneously—at individual, community, institutional and/or policy levels of influence, and that measures outcomes at two or more of these levels.

<u>Community Engagement</u>: The process of working collaboratively with and through groups of people affiliated by geographic proximity, special interest, or similar situations to address issues affecting well-being and health. Community engagement can also be seen as a continuum of community involvement. For the purposes of this NOFO, multilevel interventions should be developed and tested in collaboration with community partner(s).

Advancing Cancer Control Equity Research through Transformative Solutions (ACCERT) Consortium:

The ACCERT Consortium consists of the research teams and community partners from up to four (4) U19 ACCERT Centers and one (1) U24 Coordination Center.

<u>ACCERT Center(s)</u>: The research center(s) funded to conduct community-engaged, multilevel research interventions that address the impact of SDOH on adverse cancer control outcomes.

General Questions

1. Is a letter of intent required? What should be included?

A letter of intent is strongly encouraged, but not required or binding. Letters of intent allow NCI staff to estimate the potential review workload and plan the review. By the date listed in <u>Part 1.</u> <u>Overview Information</u>, prospective applicants are asked to submit a letter of intent that includes the following information:

• Descriptive title of proposed activity

- Name(s), address(es), and telephone number(s) of the Project Director(s)/Principal Investigator(s)
- Names of other key personnel
- Participating institution(s)
- Number and title of this funding opportunity

The letter of intent for the RFA-CA-23-026 should be sent to:

April Oh, PhD, MPH Telephone: 240-753-3154 Email: april.oh@nih.gov

The letter of intent for the RFA-CA-23-027 should be sent to: Amanda M. Acevedo, PhD Telephone: 240-276-5896 Email: <u>amanda.acevedo@nih.gov</u>

2. Are foreign components allowed?

- Non-domestic (non-US) entities and foreign institutions are **not eligible** to apply.
- Non-domestic (non-US) components of US organizations are not eligible to apply.
- Foreign components, as defined in the NIH Grants Policy Statement, are **not allowed**.

3. How will funding decisions be made?

Funding decisions will be based on the:

1) scientific and technical merit of the proposed project as determined by scientific peer review;

2) availability of funds; and

3) relevance of the proposed project to program priorities.

4. Are there priority cancer sites and/or populations that NCI is most interested in?

The NOFO does not specify any cancer sites. Responsive applications must identify and focus on communities experiencing cancer or seeking to prevent cancer and health disparities.

5. What cancer risk factors or outcomes (e.g., smoking, alcohol, etc.) are being considered for this RFA?

Each ACCERT Center must propose an overarching research theme related to addressing health equity by intervening on multilevel SDOH influences on cancer control outcomes. Themes may focus on addressing inequities related to health promotion, cancer prevention, screening, care delivery, and/or survivorship for individuals, families, neighborhoods, and communities experiencing health disparities and underserved populations. The research theme should be identified in collaboration with community partners and transdisciplinary researchers, as well as guide the selection and participation of relevant sectors and stakeholders and partners.

6. What resources can I access related to the NIH Data Management and Sharing Policy?

All applications, regardless of the amount of direct costs requested for any one year, should address a Data Management and Sharing Plan. The data/resource sharing plans must be consistent with NIH policy (with exceptions when working with tribes/tribal organizations) and follow Findable, Accessible, Interoperable, Reusable (FAIR) principles (see <u>https://www.go-fair.org/fair-</u> principles/). To learn more about what elements to include in the Data Management and Sharing Plan, please see <u>Writing a Data Management & Sharing Plan | Data Sharing (nih.gov)</u> and <u>NOT-OD-21-014</u>: Supplemental Information to the NIH Policy for Data Management and Sharing: Elements of an NIH Data Management and Sharing Plan.

7. Who do I contact with specific questions about my ACCERT project ideas?

We encourage inquiries concerning these funding opportunities and welcome the opportunity to answer questions from potential applicants. Please reach out to the Scientific/Research Contacts: April Oh (april.oh@nih.gov) or Amanda Acevedo (amanda.acevedo@nih.gov). We encourage prospective applicants to review both funding opportunities, the website, and frequently asked questions.

8. Can the same institution submit applications to both the U24 and U19 funding opportunities? While the same institution may apply to both opportunities, the investigators and direct costs across the U19 and U24 applications should not overlap. In the case that both applications are determined as meritorious for funding, any scientific, budgetary, or effort overlap for investigators would need to be reported and addressed in the just-in-time submission, as described in the <u>NIH</u> <u>Grants Policy Statement</u>.

U19 (ACCERT Research Center) Specific Questions

1. What are the main goals of the U19 ACCERT Centers?

The overall goals of this opportunity are to develop interventions that target the multilevel pathways by which SDOH influence adverse cancer outcomes; develop measures and methods to assess community-level SDOH, community engagement, and cancer control equity processes and outcomes; and build capacity among scholars from diverse backgrounds and community partners to implement interventions that incorporate the lived experiences of those who face cancer inequities.

2. What is meant by a multilevel SDOH intervention?

In the NOFO, a *Multilevel Intervention* is intervention(s) occurring at a minimum of two levels simultaneously—at individual, community, institutional, and/or policy levels of influence—and that measures outcomes at two or more of these levels. These may include multiple sectors and settings that influence cancer control and prevention outcomes. A signature multilevel intervention will focus on addressing identified *Social Determinants of Health (SDOH)*, which are the unfair and avoidable factors in health that drive health inequities. The SDOH are conditions in the environment where people are born, grow, live, learn, work, play, and age that impact health outcomes and operate at multiple levels of influence.

3. Can a U19 ACCERT Center focus on multiple SDOH?

Yes, the requirement is that the scientific focus include at least one SDOH. Applicants may choose to examine multiple SDOH as they are systems that can influence and reinforce one another.

4. How is capacity building integrated within the centers?

The Administrative Core will facilitate and lead capacity-building activities among scholars from diverse backgrounds, including those from groups underrepresented in the biomedical sciences, and community partners to implement interventions that incorporate the lived experiences of those who face cancer inequities. (See Section I. Notice of Funding Opportunity Description – Administrative Core for additional details regarding capacity-building activities).

For example, activities will support efforts to include community partners as active research team members to assist with the development of research questions for pilot studies, and the translation of scientific findings into locally appropriate language(s) and effective delivery aligned with the ACCERT Center themes.

5. Who is part of the Administrative Core?

The Administrative Core personnel should be proposed by each applicant. The Project Director/Principal Investigator and each Senior/Key personnel identified as part of the functions of the Administrative Core may be listed in this component in the application. Please see the NOFO for additional instruction on biographical sketch information. A valid eRA Commons ID account will be required for Project Directors/Principal Investigators.

6. Are pilot projects in the Administrative Core supposed to be \$50,000/year or 10% in direct costs per year (whichever is greater)?

Each ACCERT Center must have a special restricted Pilot Project Fund of \$50,000 or 10% in direct costs (whichever is greater) per year for the Administrative Core for years 2–5 for supporting participation in cross-center pilot projects. These funds must be allocated in the "Other Expenses" category on the Budget form as "*Restricted Funds for Collaborative Pilot Projects.*" Collaborative funds cannot be re-budgeted and unobligated funds, in any year, may be offset as per the recommendation from NCI program staff. NCI will retain the final approval for the release of any collaborative funds.

7. In the Administrative Core budget, are we allowed to have a Community Advisory Board and pay for travel if needed?

In the Administrative Core budget, related to travel, the NOFO states: *Travel*: Travel funds must be included in the proposed budget to support travel to Consortium-related activities, including but not limited to supporting participation of U19 Project Director/Principal Investigator and community partners (in total up to five members) to attend and participate in face-to-face annual grantee meetings during the grant cycle. Each funded research project should plan to host one annual/scientific meeting with appropriate meeting support and assistance from the Coordinating Center during the life cycle of the Consortium. The budget should include funds to support travel for new or junior investigators that are part of capacity-building activities that are established as part of the capacity-building aims and activities.

8. Is an established/experienced community network required to apply?

This NOFO requires community engagement in the development and testing of multilevel SDOH interventions. Community partners are a critical part of this funding opportunity and must be

integrated in every aspect of the program, including direct involvement in the study planning, conduct, evaluation, and publication.

Community partners within each ACCERT Center should demonstrate collaborative history with the research team(s) as evidenced by community-partnered activities with relevant outcomes (e.g., study design and implementation, communication and dissemination efforts, community education and outreach program development, etc.).

9. Can an institution submit more than one application?

Applicant institutions may submit more than one application, provided that each application is scientifically distinct.

10. Are there particular research designs that will or will not be funded by this announcement? The proposed research designs should be appropriate to assess the impact of the multilevel SDOH intervention, measures of health equity, and related cancer control outcomes at two or more levels in the study design, with an assessment and analytical plan that evaluates the cumulative as well as individual factors' effects of the SDOH and related interventions at and across each level.

ACCERT Centers Community Responsive Projects Specific Questions

1. How many Community Responsive Projects should be included in the application? How should the projects be budgeted?

Applicants are asked to describe at least one to two potential Community Responsive Projects to be conducted in the first year of the ACCERT Center Projects.

Each Community Responsive Project must be led by a minimum of two co-leaders: one scientist and one community partner. Each project leader should devote at least 1.8 person months effort (15%). Centers are required to set aside 15% of the total direct cost of the Center's budget to fund at least two projects every year over the course of the award of the Centers. These projects should run one to three years, so the two projects in each year do not have to be new projects. A minimum of three projects are required over the five-year award.

If the Community Responsive Project involves a clinical trial, the applicant is responsible for including the costs of all support for statistical design, data collection, analysis and management, data deposition into NCI or other portals and ClinicalTrials.gov, as well as costs for clinical site monitoring, project management, and quality assurance. If clinical trial costs will be covered by sources other than the U19, applicants should indicate the source of funds and provide letters of support. Specific cross-references should be made to clarify how these necessary functions will be supported. The Community Responsive Projects are administered in the Research Methods, Measures, and Data Management (RMMDM) Core.

2. Is the description of the Community Responsive Projects for the first year intended to be a brief overview, or a full proposal within the larger application?

Applicants should describe at least one to two potential Community Responsive Projects that would be conducted in the first year of the Center's projects. The focus of these research studies

should be directly linked to the focus of the Center and should have clear theoretical or conceptual bases and plans for integration of measures within the center data ecosystem. Innovative cross-disciplinary linkages and high-risk/high-payoff studies designed to advance innovative science are particularly encouraged. The project must be conducted in the first two years of the study period. Under "Section IV. Application and Submission Information," the page limits for Community Responsive Projects are listed as well as application requirements. The Community Responsive Projects should be described as part of the multicomponent application following the description in Section IV of the NOFO.

- 3. Are the Community Responsive Projects different from the large intervention proposed? Yes. The Community Responsive Projects are shorter term (1–3 years) and facilitate and enhance the research related to the Center theme of social determinants and cancer control and the signature SDOH intervention. These projects should be managed in the Research Measures, Methods, and Data Management (RMMDM) Core.
- 4. If a Community Responsive Project is not about intervening on a SDOH but related to theme, would it be responsive to the RFA?

The Community Responsive Projects are shorter term and the focus of these research studies should be directly linked to the thematic focus of the Center and should have clear theoretical or conceptual bases and plans for integration of measures within the center data ecosystem. Innovative cross-disciplinary linkages and high-risk/high-payoff studies designed to advance innovative science are particularly encouraged.

5. The RFA states that each Community Responsive Project must be led by a minimum of two co-leaders, including one scientist and one community partner. If our proposal covers work in more than one state, do we need to include one community partner from each state as a co-leader, or will one community partner be sufficient?

The application should propose the leadership team that will be most responsive to the science proposed. A minimum of one community partner, as co-leader, is required on the Community Responsive Project.

6. Should the process for selecting the Community Responsive Projects be described in the Administrative Core, or in the six pages devoted to the Community Responsive Projects? It seems that the Community Responsive Projects is part of the Administrative Core. The process for selection of the Community Responsive Projects should be described under the application component "Community Responsive Project." These projects should be managed in the Research Measures, Methods, and Data Management (RMMDM) Core, but note that the Community Responsive Projects application is a separate component under Section IV of the NOFO. The aspects of selection of a Community Responsive Project in year two should include the following as described in the NOFO: Describe the process for selection, review, and implementation of future Community Responsive Projects which may begin in year two. Applications must address areas indicated below:

- Anticipated duration of projects (up to two years but can be shorter).
- Provide examples of possible directions for research and typical attributes of anticipated projects and research and community scope of projects.

- Describe how projects will be solicited, reviewed, and prioritized for activation. In these plans, explain:
 - How the projects will coordinate with the RMMDM Core and ensure that all pilot projects fall within the overall theme of the Center (i.e., are connected to ongoing research projects);
 - Any special approaches that might be needed to provide optimized opportunities for institutions/clinics/communities;
 - Details on planned proposal solicitation frequency and format (e.g., timeline), review panel composition, basis for prioritization, etc.;
 - \circ $\;$ Logistics of the process in the context of multiple institutions.
- Describe how the projects will work with Center structure and organization to monitor, conduct, and evaluate the pilot projects to ensure compliance with all applicable regulations (e.g., annual IRB approvals, <u>Federal Wide Assurance</u> (FWA), human subjects research training, NIH clinical trials requirements, etc.) in domestic institutions.
- Describe how the Consortium-wide collaborative pilots will be coordinated with proposed projects. Specifically, describe anticipated areas for collaboration, the process for collaborative meetings, and shared data and human subjects infrastructure.

U24 (Coordination Center) Specific Questions

- What is the award budget for the U24 ACCERT Coordination Center? Application budgets are limited to \$500,000 in direct costs per year. See <u>NOT-CA-23-077</u>, a Notice of Correction to Award Budget in <u>RFA-CA-23-027</u> issued on July 10, 2023.
- Can an institution apply for both the U19 Center and U24 Coordination Center? The same institution may submit applications to this U24 RFA and its companion (<u>RFA-CA-23-026</u>; U19), as long as there is no overlap regarding investigators and direct cost funding.

3. What is the Collaborative Fund and how can these funds be used?

To facilitate synergy within the Consortium and to achieve unmet scientific priorities, awardees of the ACCERT Consortium must budget specified funds designated as "Collaborative Funds" for Consortium-wide activities. The Coordination Center will facilitate and manage "Collaborative Funds" for Consortium-wide activities or pilot project(s) to support new transdisciplinary research questions that emerge from the Consortium.

4. Are applicants required to budget for annual meeting attendance?

Yes, for the U24, applicants will be required to budget for key personnel and team members/collaborators (in aggregate, up to three members, which may include one trainee and one community partner) to attend one annual face-to-face investigator meeting.

Questions About eRA Commons

1. Where can I find help in submitting my application to the NIH eRA Commons ASSIST system? All applications must be submitted via the NIH eRA Commons ASSIST system. For help with the system, visit <u>https://www.era.nih.gov/help-tutorials/assist/era-training-assist.htm</u>. Customer support can be reached at 1-866-504-9552 (toll-free) (press 1 for eRA Commons or ASSIST) or 301-402-7469 (press 1 for eRA Commons or ASSIST). If you need immediate help (i.e., you are within two days of a deadline or in the event of a security emergency), call customer support. Note that the Service Desk's busiest hours are between 10:00 a.m. ET and 3:00 p.m. ET, and hours of operation are Monday through Friday, 7:00 a.m. to 8:00 p.m. ET (closed on <u>federal holidays</u>).

 Where can I find help in registering my community organization in eRA Commons? Register your organization, as well as the Business Official/Signing Official and Principal Investigator roles, within eRA Commons: <u>https://www.era.nih.gov/register-accounts/register-in-era-</u> <u>commons.htm</u>

If an individual is to be listed on an application as a **Co-Investigator, Senior/Key Personnel, Other Significant Contributor, Collaborator, Consultant, Sub-Awardee, etc. (i.e., research partners, community partners, consultants, etc.)**, they will need to have a valid eRA Commons username (Commons ID). The Business Official/Signing Official roles of the applicant organization have the authority to <u>create and edit eRA Commons accounts</u>.

For questions regarding the <u>eRA Commons</u> registration process, contact the eRA Service Desk at 1-866-504-9552 (toll-free) or 301-402-7469 from Monday through Friday, 7:00 a.m. to 8:00 p.m. (ET). Please let them know you are applying to OTA-22-007. If you need immediate help (i.e., you are within two days of a deadline or in the event of a security emergency), call customer support. Note that the Service Desk's busiest hours are between 10:00 a.m. ET and 3:00 p.m. ET, and hours of operation are Monday through Friday, 7:00 a.m. to 8:00 p.m. Eastern Time (closed on <u>federal holidays</u>).

3. Which key personnel need to have an eRA Commons account?

The applicant organization, Signing Official, and Principal Investigator must have an eRA Commons account. Once the "Signing Official" has been designated in eRA Commons, they can establish new accounts for individuals at their organization and add roles to an existing account. Detailed instructions can be found in the Instruction Guide for OTA Submissions via ASSIST (version 11/03/22) at https://www.era.nih.gov/help-tutorials/assist/era-training-assist.htm.

Other key personnel can also have eRA Commons accounts, but it is not required at the time of application submission.