## Frequently Asked Questions for NCI U54 Cancer Health Disparities and Minority Health (CHD-MH) SPORE <u>RFA-CA-24-020</u>

### Eligibility

- 1. What institutions are eligible to apply for the <u>U54 SPORE RFA</u>? Are only NCI-designated cancer centers eligible to apply?
  - Domestic for-profit or non-profit institutions/organizations and local or federal governments are eligible
    to apply for the U54 SPORE RFA (see examples of <u>eligible applicants</u>). The RFA is <u>not</u> exclusive to NCIdesignated cancer center applicants.
  - The following types of higher education institutions are always encouraged to apply for NIH support as public or private institutions of higher education: Hispanic-serving Institutions, Historically Black Colleges and Universities, Tribally Controlled Colleges and Universities, Alaska Native and Native Hawaiian Serving Institutions, and Asian American Native American Pacific Islander Serving Institutions.
- 2. I am currently a PD/PI (or MPI) on a P50 SPORE. Can I also be a PD/PI (or MPI) on a U54 SPORE?
  - Investigators may serve as a PD/PI (or multi-PI) on only one funded U54 or P50 SPORE at a time.
     However, investigators may have other roles (i.e., co-leader, Core director) on multiple U54 or P50 SPOREs concurrently, even from more than one institution (see eligible applicants).

## **Scientific Focus**

- 3. Can a U54 SPORE address more than one cancer health disparity or cancer type in different underserved/underrepresented populations?
  - Yes, a U54 SPORE application can investigate more than one cancer health disparity or cancer type in different underserved populations among its proposed projects (see <u>RFA definitions</u> for cancer health disparities, minority health, and underserved populations).
- 4. Can you propose cancer health disparities projects and minority health projects in one application?
  - Yes, a U54 SPORE application can have a combination of cancer health disparities projects and minority health projects (see <u>RFA definitions</u> for cancer health disparities and minority health).
- 5. Is there a desired number of disease sites within an application?
  - No, applications can choose to focus on one organ-specific cancer or propose projects focused on different organ-specific cancers.
- 6. What are examples of projects that are responsive to the <u>U54 SPORE RFA</u>?
  - The U54 SPORE RFA supports cancer health disparities and minority health translational research in populations who are underserved and or underrepresented (see <u>RFA definitions</u>). Some examples of previously funded SPORE research this area include the P20 Cancer Health Disparities SPOREs: https://trp.cancer.gov/spores/cancer\_health\_disparities.htm.
- 7. Even though a clinical trial is not required for U54 SPORE projects, should projects show a clear path to a clinical trial?
  - Projects should have strong translational potential, meaning the project has high potential to impact
    patient care, clinical practice, public health, etc. by achieving one of the six eligible SPORE human
    endpoints (see <a href="RFA">RFA</a> definition for human endpoint). Therefore, U54 SPORE projects do not have to
    propose or lead to a clinical trial as a human endpoint to have high translational potential or impact.
    Examples might be a study of risk assessment of an underserved population for a specific cancer or
    biomarker development using human biospecimens.
- 8. Can projects focus on underserved and/or underrepresented populations not listed in the RFA?
  - Projects should propose research in populations who are underserved as <u>defined in the RFA</u>.
- 9. Are SPORE projects expected to have integration or synergy like P01 grants?
  - No, U54 SPORE applications can propose projects with independent research topics. Synergy and integration requirements of P01 grants do not apply to the U54 SPORE grant mechanism.

#### **RFA Requirements**

#### 10. How is the SPORE Director's effort allocated?

• SPORE PD/PI (or SPORE Director) effort can be an aggregate of effort in different components. For example, a SPORE Director can meet the 2.4 PM effort requirement with 1.2 PM on a Project and 1.2 PM effort in the Administrative Core.

#### 11. Does the <u>U54 SPORE RFA</u> have EPPS or CHD-MH incentive funding like the <u>P50 SPORE PAR</u>?

No, the U54 SPORE RFA does not include incentive funding options described in the P50 SPORE PAR.

## 12. Should the Developmental Research Program (DRP) and Career Enhancement Program (CEP) have the same Director(s)?

• DRP and CEP Directors should be selected based on their expertise to lead the program. Therefore, the DRP and CEP could have the same or different Directors.

### 13. Does the RFA require an NIH Plan to Enhance Diverse Perspectives (PEDP)?

• No, a PEDP is not required for the U54 SPORE RFA.

## 14. How does the <u>U54 SPORE RFA</u> differ from the <u>P50 SPORE PAR?</u>

• Please review the following comparison chart:

	P50 SPORE	U54 CHD-MH SPORE
Minimum 3 Translational Research Projects	Yes	Yes
Administrative Core	Yes	Yes
Biospecimen/Pathology Core	Yes	Yes
Scientific Collaborations	Yes	Yes
Dev. Research Program & Career Enhancement Program	Yes	Yes
Community Outreach and Engagement (COE) Core	No	Yes
Community Advisory Board	No	Yes
Coop. Agreement Program Coordinating Committee	No	Yes
Human Endpoint (in each Project)	Yes	Yes (e.g., pilot/feasibility studies)
NIH-Defined Clinical Trial	Yes	Optional
Project Co-Leadership (Basic and Applied)	Yes	Yes (e.g., epidemiologists or social scientists)
Budget Cap	\$1.4M DC	\$1.6M DC

## 15. Is there an ideal number of projects to submit?

• No, SPORE applicants should a minimum of three projects (no more than five). However, applicants should submit their most meritorious research projects that are responsive to the RFA.

## 16. Do SPORE project basic co-leaders have to have an active laboratory?

• The basic co-leader will lead the basic research aspects of the SPORE project. This is described in the project budget justification and basic co-leader's biosketch. Additionally, basic co-leaders should be able to execute or lead the basic research studies proposed for the project. That could be demonstrated by having an active (wet) laboratory in the research area or having the specific expertise in the basic research study area(s) proposed for the SPORE project. Therefore, having an active wet lab is not a requirement.

## 17. Do all project co-leaders have to have an independently funded peer-reviewed grant or serve as overall/site chairperson on an active NCI clinical trial in the SPORE research area?

No, only four individuals among the Project Co-Leaders, Shared Resources Core Directors, and SPORE Directors must serve as PDs/PIs (or project leaders) on peer-reviewed research grants (e.g., R01, R21, P01, U01, U10, U19, American Cancer Society [ACS], U.S. Department of Defense [DOD], or equivalent) or serve as overall chairpersons or site chairpersons on an active NCI-sponsored clinical trial. These

activities must be directly related to the cancer(s) being investigated in the SPORE or the specific expertise required for the SPORE, including CHD-MH (see RFA minimum research base requirement).

## 18. Can a project have more than one basic co-leader? Can a project have more than one clinical/applied co-leader?

Yes, projects can have more than one basic co-leader or more than one clinical/applied co-leader.

# 19. What is the difference between the required NIH Data Management and Sharing Plan and the RFA's Data Systems plan?

- The <u>Data Management and Sharing Plan</u> (DMS) is a required attachment that applies to most NIH grant
  applications. It includes 6 elements plus a genomic data sharing plan element. The DMS plan is attached
  to the Overall component and is not seen nor reviewed by the peer review panel. It will be reviewed by
  Program staff if the grant is selected for funding.
- The Data Systems (DS) plan is a SPORE-specific attachment in the Administrative Core that is peer reviewed and supports data activities (see <a href="RFA Administrative Core">RFA Administrative Core</a>). In some instances, the DS plan will repeat the elements of the DMS plan so that the reviewers can ensure the projects and core are adequately addressing data management, access, control, preservation, and storage. The plan will focus on the SPORE bioinformatics capabilities and SPORE data management capabilities, systems, platforms, and tools needed to support human and non-human research within the Projects and Cores, as they relate to the cancer center, institution, or activities of other NIH/NCI initiatives. Additional criteria are required for projects with clinical trials.
- Costs associated with the DMS and/or DS plans should be requested within the Administrative Core. Personnel cost associated with either plan should be charged to the appropriate project or core.

## **Budget**

#### 20. What is the maximum budget for the application?

• The maximum U54 SPORE budget is \$1.6M direct cost. Subaward F&A does not count toward direct cost. Second and third tier subawards are allowed.

#### 21. Does the U54 SPORE use a modular budget?

• The U54 mechanism uses a <u>multi-project</u> grant mechanism that requires a detailed budget and justification.

#### Submission

#### 22. What is the application due date for the U54 SPORE RFA? Will the RFA be reissued?

- There is only one receipt date for the RFA: September 26, 2024.
- It is not known whether the RFA will be re-issued.

#### 23. How many applications can our institution submit?

NCI program is requesting only one U54 SPORE submission per institution.

#### 24. Is a letter of intent (LOI) required for submission?

An LOI is optional but strongly encouraged, as it allows NCI to prepare for the number of applications
coming in, assess the scientific areas of research, and begin recruiting reviewers for the special emphasis
panel (see LOI details).

#### **Peer Review**

#### 25. What is the peer review process for the U54 SPORE?

• All U54 SPORE applications will undergo peer review by a special emphasis panel (SEP). For the U54 SPORE SEP, peer reviewers will be recruited based on the specific expertise and research area of each application. U54 applications will not be reviewed together with P50 SPORE applications.

#### 26. How do I indicate areas of expertise needed for the peer review of my application?

 Applicants are encouraged to use the <u>PHS Assignment Request Form</u> to state the specific expertise needed for the peer review of their application.

#### 27. Who do I contact regarding peer review questions?

 Prior to submission, please contact <u>Dr. Leah Hubbard</u> with questions regarding your application and peer review. Post-submission, please contact the Scientific Review Officer (SRO) assigned in your eRA Commons account.

## **NCI Consultations**

#### 28. Are pre-application consultations with NCI program required for submission?

- While not required, it is strongly encouraged that you schedule an individual pre-application consultation
  with NCI program to assist in confirming programmatic compliance of your proposal with the U54 SPORE
  RFA. And while not always possible, we recommend you schedule this meeting after your external
  advisory board has reviewed your projects and plans.
- NCI program offers both scientific and administrative pre-application consultations. During the scientific
  consultation, you will discuss your proposed SPORE program, project aims, cores, and CEP/DRP with NCI
  program staff. During the administrative pre-application consultation, NCI program will discuss NIH
  policies and guidelines related to preparing and submitting a SPORE application. To schedule a scientific
  pre-app, please contact <u>Dr. Leah Hubbard</u>. To schedule an administrative pre-application consultation,
  please contact <u>Ms. Tamara Walton</u>.

# 29. Who should I contact to have a discussion with NCI program about potentially submitting a U54 SPORE application?

• If you have scientific inquires related to the U54 SPORE RFA and your proposal, please contact <u>Dr. Leah Hubbard</u>. If you have administrative inquires or questions related to NIH data management and sharing policies, please contact <u>Ms. Tamara Walton</u>.