

**RFA-CA-20-030 Utilizing Cohort Studies to Address Health Outcomes in Cancer Survivors
(UG3/UH3 Clinical Trial Not Allowed)**

Mechanism	UG3/UH3
Leadership	Single or Multiple PI
Clinical Trial Requirement	Not Allowed
Aims	<p>This FOA requests applications to support research in new and innovative cohort studies that identify clinical, lifestyle, genomic, and other factors that affect health outcomes (e.g., morbidity, mortality, quality of life, physical, social, and psychological outcomes) in cancer survivors (i.e., from diagnosis to the end of life). This FOA supports the creation of a new prospective cohort study that addresses a gap in knowledge pertaining to the health of cancer survivors. Applications must identify the scientific gap that the study addresses, which may include emerging treatments, less common cancer sites, and/or understudied populations of cancer survivors with disparities.</p>
Populations	<p>Research must focus on cancer survivors. The National Cancer Institute's Office of Cancer Survivorship defines a cancer survivor as any individual from the time of cancer diagnosis through the balance of his or her life. There are many types of survivors, including those living with cancer and those free of cancer.</p>
Study Requirements	<p>To be responsive to this FOA, proposed projects must include:</p> <ul style="list-style-type: none"> • Appropriate measures of relevant exposures, outcomes, and treatment information that can inform the health of cancer survivors. • Information about specific therapies and cumulative doses. • Recurrence as a disease endpoint, unless there is a strong justification why it is not possible or relevant to the study; • Research questions that examine the cancer survivor experience with data collection in the following domains (the depth of each domain may vary from minimal to extensive): disease characteristics (e.g., type, stage, tumor biomarkers); individual survivor characteristics (e.g., comorbidities, socioeconomic status, social connections, information seeking, access to care measures); treatment, treatment-related effects, and follow-up care (e.g. dose, adverse events, palliative care); behavioral and lifestyle factors (e.g., diet, physical activity, adherence); and quality of life outcomes (e.g., HRQOL, patient symptom reports); and

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	<ul style="list-style-type: none">• Demonstration of research question novelty and importance in the application.
Budget Considerations	Application budgets are limited to \$750,000 direct costs per year in years 1 & 2. Budgets in years 3-6 are not limited but need to reflect the actual needs of the proposed project.
Scientific Contacts	Joanne Elena (elenajw@mail.nih.gov)

Application FAQs

Is the letter of intent required?

Yes. A letter of intent (LOI) is strongly encouraged for RFA-CA-20-030. LOIs assist NCI in identifying expert reviewers without conflicts of interest. **Letters of intent are due 30 days prior to the receipt date.**

Letters of intent should include the following:

- Descriptive title of proposed activity
- Specific Aims for the proposed project
- Name(s), address(es), and telephone number(s) of the PD(s)/PI(s)
- Names of other key personnel
- Participating institution(s)
- Number and title of this funding opportunity

The LOI should be sent by email, with the subject "Letter of Intent for RFA-CA-20-030" to Joanne.Elena@nih.gov

I have specific questions about my project. What should I do?

Please email Joanne Elena at Joanne.Elena@nih.gov to discuss project specific questions and include an abstract/specific aims.

Are international institutions allowed to apply? What about international partners and/or subcontracts?

Yes, international institutions and collaborators are eligible to apply to this FOA; however, priority will be given to studies with direct relevance to the U.S. cancer survivor population. Non-domestic (non-U.S.) Entities (Foreign Institutions) are eligible to apply.

Non-domestic (non-U.S.) components of U.S. Organizations are eligible to apply. Foreign components, as defined in the NIH Grants Policy Statement, are allowed

Are there any criteria on the number of collaborating institutions?

There is not a requirement for the number of investigators or collaborating institutions. Both single and multi-PI applications, as well as, single and multi-institute applications are eligible.

What should be included in the data sharing plan?

All applications, regardless of the amount of direct costs requested for any one year, should include a data sharing plan in the Resource Sharing Plan attachment that is compliant with the 2003 NIH Data Sharing Policy. If large scale human genomic data are being collected, the data sharing plan must also comply with the 2015 NIH Genomic Data Sharing Policy.

The Data Sharing Plan is expected to include:

- The extent and type of data that will be shared
- The data repository to which the data will be submitted (not limited to NIH repositories)
- The timeline for the data to be shared after each round of data acquisition

Applicants are required to maintain a website that details the procedure for external investigators requesting and obtaining data; procedures and criteria for access must be compliant with the above referenced NIH data sharing policies. Applicants are encouraged to consider [NIH data repositories](#) for sharing data with external investigators. A summary of the number of data requests, acceptances, and rejections should be provided in annual progress reports to NCI. The Data Sharing Plan should address participants' study consents and include (whenever possible) the option to use data and/or biospecimens for future research studies.

Is an Awaiting Receipt of Application (ARA) required for budgets that exceed \$500K direct costs in any of the grant years?

No, the ARA policy does not apply to RFAs.

Does Early Stage Investigator (ESI) or New Investigator (NI) status apply to this FOA? Will NI or ESI investigators be considered too “junior” to lead a competitive application?

Yes, ESI/NI statuses apply. In grant applications that involve more than one PI (e.g. multi-PI), all PD/Pis must meet the definition of NI or ESI for the application to be designated as such. NCI is committed to supporting Early Stage Investigators (ESIs) and will place special emphasis on supporting ESI-designated applications.

No, ESI/NI investigators are not too junior to compete for this U01. For a successful grant application, it is imperative to clearly demonstrate that the named key personnel have the expertise required to accomplish the studies proposed.

Is it expected that at least one aim has clinical recurrence as a main endpoint? Are biomarkers or intermediate prognostic indicators of high recurrence risk acceptable, given the time frame?

Recurrence certainly may be an endpoint but is not required. Recurrence data must be collected, unless there's strong justification.

Is this RFA going to be re-issued with additional dates?

No. This RFA currently has one submission- July 7, 2020.

Are registries required for recruitment?

No. Use of population-based cancer registries for recruitment is strongly encouraged for broad representation. Use of registries is required as a comparison to assess the representativeness of the proposed study population compared to the relevant cancer survivor population.

Are all 5 data domains required for all grants?

Yes, all 5 domains must be addressed in the application. The breadth and depth of the domains will differ based on research questions. For example, in the individual survivor characteristics domain, it may be appropriate for a treatment toxicity research question to collect comorbidities and a recurrence research question to collect access to care measures.

Will applications be reviewed by a standing study section or a special emphasis panel?

All applications will be reviewed in a special panel designed for this FOA.

Are 2 sets of specific aims needed for the UG3 and UH3 phases?

No, one set of scientific specific aims will guide the entire application. Milestones are required for transition from the UG3 to UH3 phase.

Mechanism & Budget FAQs

Is there a suggested budget for Years 3-6?

There is no suggested budget or budget limit; however, the budget must reflect the actual needs of the proposed project.

Will the UG3 phase be fully funded (no budget cuts) or if there are cuts can the milestones be altered?

Budget cuts will depend on the FY21 Funding Policy which has not been set. The ability to alter milestones will depend on the cut and will be discuss on a case by case basis.

How many sets of aims are needed for the UG3/UH3 mechanism?

One set of aims should guide the grant over both the UG3 and UH3 phases. Milestones are required for transition from the UG3 to UH3 phase.

How many milestones are required?

Milestones must demonstrate feasibility for recruitment and data collection/use. The number of milestones will vary based on individual research programs. In general, we expect 2-3 milestone that are specific and measurable. Milestones should be robust enough to demonstrate feasibility, yet attainable.

Are there any preferences for observation versus intervention studies for the UH3 phase?

Only observational studies are responsive to this FOA. Embedded trials within cohorts are also not allowed. The research question should inform future interventions, clinical guidelines, and patient management strategy development to improve outcomes in cancer survivors.

Should the UG3 phase milestones be specific in the Research Strategy or in the Timeline for Human Subjects Plan?

Per the FOA, the milestones should be included in the Research Strategy Sub-section E. Milestones and Timelines.

Should recruitment be completed during the UG3 phase?

No. Recruitment during the UG3 phase needs to meet the milestones set in the application and demonstrate feasibility of recruiting the planned population and collecting the study measures.

Can costs used to encourage participation by recruited survivors be included in the budget?

Yes, subject incentives can be included in the grant budget.

Research Scope FAQs

What is the difference between the Cohort Infrastructure PAR (20-136) and this current RFA (CA-20-030)?

The Cohort Infrastructure PAR supports basic maintenance for infrastructure of existing cohorts; whereas this FOA supports the new prospective cohorts. In addition, the PAR does not support the conduct of hypothesis-based research question and this FOA requires scientific research aims.

Will the collection of biomarkers be acceptable?

Biomarker collection is acceptable when it supports the research question being addressed in the application. Biomarker collection that is not directly related to the research question is not acceptable.

What projects will be considered non-responsive to this FOA?

Applications are considered non-responsive if they are:

- based on secondary use of existing cohort data
- use a study design that is not a prospective cohort
- or exclude data collection from any of the five domains
- do not meet the requirements stated in the RFA

What projects will be prioritized?

Applications that aim to identify and/or address clinical, lifestyle, genomic, and other factors that affect health outcomes in rare cancers, understudied populations and understudied treatments (e.g. newer treatments and combination therapies) are of high interest.

How do I know what is in the NCI portfolio?

A list of currently funded cohorts is available on the [EGRP website](#) and all funded applications are available on [NIH RePORTER](#).

Is preliminary data required for all applications?

Yes, like R01 applications, pilot and feasibility data are required to support the research question and approach.

Would problematic late effects from older cancer treatments be a priority for funding (e.g., peripheral neuropathy)?

If the older treatments continue to be used in the majority of the population and the research question has not been addressed, it would be responsive. If older treatments are being used in new therapy combinations, it would be responsive.

Is a cohort aimed at developing biomarkers and genetic predictors for risk of developing a late effect (e.g., peripheral neuropathy) be suitable for this FOA?

As long as the requirements of the RFA are met, the inclusion of biomarkers and genetic data to study late effects would be eligible.

Is it acceptable to meet just one of the identified gap areas (e.g., rarer cancers, understudied populations) or will studies that meet multiple gaps be prioritized?

Yes, meeting one gap is sufficient.

Research Population FAQs

Please define cancer survivor.

The National Cancer Institute's Office of Cancer Survivors defines a cancer survivor as any individual from the time of cancer diagnosis through the balance of his or her life. There are many types of survivors, including those living with cancer and those free of cancer.

Are you primarily interested in adult onset cancers? Would childhood cancers be responsive?

All applications that meet the requirements stated in the RFA, including meeting a demonstrated gap in the NCI portfolio, are responsive. We have identified more gaps among adult onset cancers, but studies of childhood cancers that meet the requirements are welcome.

Are childhood cancers considered 'rare' for the purposes of this funding announcement?

There is no requirement that applications submitted to this FOA focus on rare cancers. However, they must address a gap in knowledge pertaining to cancer survivors. Thus, if the application is focused on childhood cancers and addresses a gap in knowledge, the application meets the requirements of the FOA.

What would be the ideal size of the cohort?

The size of the cohort is determined by the sample size needed to answer the proposed research question.

Does the cohort of cancer survivors need to be population-based or hospital-based (or either)?

The use of population-based cancer registries is strongly encouraged for broad representation. If the cohort is hospital-based, the use of registry data is required as a comparison to assess the

representativeness of the proposed study population compared to the relevant cancer survivor population.

Is the goal of this funding announcement to focus on patients undergoing active treatment at enrollment or are cancer survivors encouraged?

Studies of all cancer survivors (time of cancer diagnosis through the balance of life) are eligible, including patients undergoing active treatment and of longer-term survivors. All studies must address a gap in knowledge pertaining to cancer survivors.

Where can you find the list of cohorts of cancer survivors funded in the NCI portfolio?

A list of currently funded cohorts is available at:

<https://maps.cancer.gov/overview/DCCPSGrants/grantlist.jsp?method=portfolio&owner=rogerssc&portfolio=Cancer%20Epidemiology%20Cohorts>).

Would it be beneficial to use existing government data resources, or should applications build upon existing cohorts with new data elements?

Where feasible and appropriate to the research questions proposed, the use of existing resources is acceptable and encouraged to minimize costs.

Is it acceptable to recruit from a previously recruited cohort (e.g., 5-year survivors after their initial recruitment at diagnosis)?

Yes, but there must be new recruitment and substantial new data collected to establish a “new” cohort.

Is it expected that at least one aim has clinical recurrence as a main endpoint? Are biomarkers or intermediate prognostic indicators of high recurrence risk acceptable, given the time frame?

Recurrence certainly may be an endpoint, but that is not required. Recurrence data must be collected, unless there’s strong justification.