



2015-2016 (v5)

Opportunity Fund Announcement Materials

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2. Application Instructions
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Overview

The Cancer Research Network (CRN) invites applications for Opportunity Fund Projects that have as clear objectives and outcomes the submission of cancer-related R01 or similar applications for grant funding. All projects must involve population sciences research – epidemiologic studies or health care services research, broadly defined – that is conducted within the integrated health care settings of the [CRN and its affiliate sites](#). Basic laboratory or population sciences research that does not include activities in the CRN or Health Care Systems Research Network (HCSRN) setting is ineligible.

The expectation is that investment in Projects will lead to fundable research applications or proposals. Projects must clearly indicate plans for conducting work that results in an eventual application for funding, such as for an R01 or other research award from the NIH or other funding agencies with a competitive peer-review process.

NOTE: “R01 or similar applications” refers to any applications that are submitted to a funding agency with peer-review*, and may include responses to specific funding opportunity announcements. In the NIH context, this may include applications for other grant categories, such as P01’s or U01’s. Applications that have as their objective the submission of R03 or similar small grant applications are outside the scope of this solicitation.

*See a list of funding agencies with peer review here:

<http://cancercenters.cancer.gov/documents/PeerReviewFundingOrganizations508C.pdf>

Objectives

This solicitation is focused specifically on support of activities that will result in submission of an R01 or similar application for grant funding. As such, it is expected that the scope of activities for any given Project application will be clearly focused and time-limited – on the order of a few months, with a maximum of 12 months.

The range of activities that may be supported under solicitation may fall under topics such as:

- Collection of pilot data to support specific objectives in the planned R01 submission;
- Demonstration of ability to carry out one or more key aspects of the planned R01 submission;
- Support for collection of qualitative data to support a planned R01 submission, such as conduct of key informant interviews or a focus group;
- Collection of key data or experience to respond to reviewer comments from a previously-submitted R01-type application that is planned for resubmission;
- Convening an in-person meeting of key investigators or other stakeholders to respond to funding opportunity announcements, such as a Request for Applications from the NIH or AHRQ or a PCORI Funding Announcement;

These are examples of the types of activities that will be supported. Other activities that fit the intent of this Call for Applications will also be considered for funding.

Who can apply?

Any investigator at a qualified research institution, regardless of prior involvement with the CRN or its member institutions is eligible to submit Opportunity Fund applications and be funded under this program. Qualified research institutions are institutions that are eligible to receive grants from the National Institutes of Health and include, but are not limited to, CRN Sites or affiliate Sites, academic health centers, schools of medicine or public health, NCI-designated cancer centers, and other research organizations.

If the Principal Investigator of the application does not have a primary appointment at one of the CRN or its affiliate sites, **the proposed project must include a co-investigator who does have such a primary appointment.** The CRN requires that any research conducted in the CRN setting, including Opportunity Fund Projects, involves the approval of investigators at participating CRN Sites. If you need assistance establishing collaborations with CRN investigators, please contact the Coordinating Center at cancer-research-network@kp.org.

Opportunity Fund Projects Evaluation Criteria

Applications will be judged by the following criteria:

- Activities that are in line with overall CRN aims – population sciences research -- epidemiologic studies or health care services research, broadly defined -- that is conducted within the integrated health care settings of the [CRN and its affiliate sites](#);
- Activities that clearly will result in submission of a potentially fundable R01-type research grant application;
- Timeliness and readiness: there is a clear planned submission date and requested funds will support activities that will support an application that meets that submission date;

In addition, funding decisions may also consider the following:

- Scientific focus in one of the four CRN strategic areas as represented by the [CRN Scientific Working Groups](#);
- Leverages unique features of the CRN and HMO setting;
- Inclusion of clinicians in the planned R01;
- Inclusion of collaboration with a research partner institution outside CRN and affiliated sites;
- Planned R01-type application has clear practice impact or translational potential.

Funding

Approximately \$300,000 is available to fund Opportunity Fund Projects in this round of funding. We expect to fund eight or more projects.

- The number of projects funded assumes receipt of meritorious applications.
- Projects should have budgets of no more than \$25,000 in Direct Costs (including Direct Costs for any consortium or subcontract institutions); any exceptions must be discussed before submission with the CRN Principal Investigator, Dr. Lawrence Kushi, and the CRN Executive Committee.

- In addition to Direct Costs, your institution's full Federally-negotiated Indirect (Facilities and Administrative) costs are allowed.
- Opportunity Fund Applications with a focus on convening a planning meeting are limited to \$10,000 in Direct Costs.

This program is supported by funds awarded to the CRN by the National Cancer Institute (NCI). Any Opportunity Fund Projects that are awarded are subject to all regulations that pertain to receipt of NIH funds, including IRB approvals or documentation of filing of preparatory-to-research notifications, if necessary, prior to initiation of activities under the Project.

The performance period for Opportunity Fund Projects funded under this solicitation will vary, and are expected to be no longer than several months. Regardless, no applications will provide support for more than one year. Depending on the nature of activities, projects may be funded as subcontracts to the applicant organization(s) from Kaiser Permanente Northern California (KPNC) through the Kaiser Foundation Research Institute (KFRI). Select activities (e.g., travel expenses associated with convening an in-person meeting) may be supported directly through the prime CRN grant from the NCI.

Although subcontracts for Opportunity Fund Projects will be established as soon as possible after funding decisions are finalized, administrative processes and associated timelines may result in some delay in implementation of subcontracts. For planning purposes, CRN Opportunity Fund Project applications should plan to initiate activities no sooner than approximately two months after submission of the application.

Meritorious applications that meet the intent of this Call for applications will be funded unless funds are no longer available in this Fiscal Year.

Opportunity Fund Application Process

Submission Due Date

Applications will be accepted and reviewed on a rolling basis. However, a final due date for the CRN Fiscal Year 2015-2016 (ending Aug 31) will be March 15th.

Review Process

Applications received will be reviewed administratively to ensure alignment with application guidelines and objectives. If the application requires modification, the applicant will be notified with the opportunity to resubmit the application, unless the planned activities are outside the intent of this Call for Opportunity Fund Applications.

After Administrative Review, the application will be sent to up to four individuals who will review the application for the criteria noted above and detailed in the Review Process. The reviewers will provide a recommendation to fund or not fund a specific application.

On a monthly basis, typically at its monthly meeting held on the second Wednesday of each month, the CRN Steering Committee will review all applications that are recommended for funding and make the final decision regarding funding.

Overall, we hope to have funding decisions made within no more than four to six weeks from date of submission. If an Opportunity Fund Application is on a particularly tight timeline (e.g., because of response to a funding opportunity announcement with an imminent deadline), an expedited review process may be considered.

Questions during Preparation of Proposals

We have prepared a list of frequently-asked questions on the Opportunity Fund Projects Program, included in this packet.

For general information on the CRN, please view our [three-part video series](#).

If you have any additional questions, please contact the [CRN Coordinating Center](#).

Research Focus

The main objective of the CRN Opportunity Fund is to catalyze applications for R01-type grant funding. Projects are invited that address cancer research questions across the spectrum of cancer control, from primary prevention and screening, through treatment, survivorship, and end-of-life care.

We particularly encourage projects that fall under the CRN scientific areas, which include Prevention & Screening; Epidemiology of Prognosis & Outcomes; Health Care Quality & Cost; or Communication & Dissemination. The CRN has established [Scientific Working Groups](#) to promote research in these areas, and their leaders and members are available to provide support or otherwise help navigate the CRN.

Opportunity Fund Projects that may address topic areas that are outside the focus of or address the interests of more than one of the Scientific Working Groups are also invited. We recognize that there are many important research questions that may be addressed in the CRN context.

Application Due Date

Applications will be accepted and reviewed on a rolling basis. However, a final due date for the CRN Fiscal Year 2015-2016 will be March 15th.

Application Submission

Applications can be submitted here: [Opportunity Fund Application Form](#)

Application Format

Formatting Requirements:

The application must be submitted using [PHS398 forms](#) linked to on the NIH website.

The Opportunity Fund application should follow general NIH application formatting requirements. All text should use the Arial typeface with a font size no smaller than 11 point. Tables and Figures should use font sizes no smaller than 9 point. Line spacing should be no less than single spacing. Include the name of the Principal Investigator in a header on all pages, and page numbers centered in the bottom of the page. Margins should be no smaller than 0.5 inches.

The Opportunity Fund application should be submitted as a PDF document; a single compiled and indexed PDF document to allow rapid navigation to the Specific Aims and Research Strategy (and other application sections) is preferred.

NOTE: The application does NOT require formal institutional approvals and signatures at the time of submission for review purposes. This will be required for successful applications as part of the subcontracting process. However, applicants may need to consult with their grants administration offices to ensure that preparation of budgets follows correct assumptions, and also so that relevant personnel are ready to initiate subcontracting procedures in the case of successful funding.

NOTE: All Opportunity Fund applications must include a draft Specific Aims (or equivalent) page for the planned R01-type application. This draft Specific Aims page must follow the Research Strategy section of the application.

NOTE: The CRN has a Prep-to-Research Process in place. If you are planning to submit an R01 or other grant and your request or project preparatory work can be accomplished through this process, please submit a PTR form to cancer-research-network@kp.org. The completion of these requests is considered CRN infrastructure work and is of no cost to the investigator. [Prep-to-Research Form](#)

The Opportunity Fund application should include the following:

- The **Face Page** (PHS398 Form Page 1) including its required components:
 - Title of Application.
 - Name and affiliation of Principal Investigator.
 - Formal institutional approval and signatures may be required.

- A Face Page should be included for all collaborating organizations for each Opportunity Fund application.
- **Description, Performance Sites, Key Personnel** (PHS398 Form Page 2) should include:
 - Abstract of Opportunity Fund.
 - Include as the last sentence the specific targeted submission date for the planned R01-type application. An example sentence is something such as: “This Opportunity Fund will support an R01 application to the NCI that will be submitted on June 5, 2016.”
 - Names, roles, and affiliations of key personnel, starting with the Principal Investigator and including any co-investigators.
- **Table of Contents** (PHS398 Form Page 3), including a listing of any appendices (see below for any *required Appendices*).
- The **Budget and Justification** (PHS398 Form Page 4) must be provided as a **detailed budget**.
 - Provide separate budgets and budget justifications for each institution involved in the Project.
 - The PI institution budget should also include the compiled summary budget, with any other institutional budgets entered under consortium/contractual costs.
 - As funds will be awarded as subcontracts to each participating institution, administrative subcontract costs should not be included in the PI institution budget. For example, prime applicant institution F&A costs cannot be applied to the first \$25,000 of budgets for any collaborating institutions. Any budget that includes such expenses will be considered non-responsive and not reviewed.
 - Modular budget requests will be considered non-responsive and not reviewed.
 - NOTE: As this application is for no more than one year of support, the PHS398 Form Page 5 (Budget for the Entire Proposed Period of Support) is not required.
- **NIH-format Biosketches** for the Principal Investigator and all key personnel. Do not exceed five pages for any individual. Please use the format under current use for NIH applications.
- **Resources and Environment** Section for any institution that is not a CRN Site. Resources and Environment Sections for CRN or Affiliate Sites may be included but are not required.
- A **Checklist** must be included for each participating institution.

RESEARCH PLAN

- **NOTE:** The **Specific Aims** of the Opportunity Fund will be considered part of the Research Strategy and do not need to be on a separate page. This differs from general NIH application instructions.
- The **Research Strategy** Section should be **no more than three pages total**, and should be organized in the following sequence:
 - Objectives/Specific Aims:
 - Outline the main objectives that will be undertaken under these Project funds
 - Significance:
 - In no more than one paragraph, outline the significance of the proposed Project activities to enhance submission of the R01-type application
 - Innovation:

- In no more than one paragraph, briefly describe the innovation of the planned R01-type application.
- Planned R01-type application:
 - Applications must specifically outline the planned future grant application(s) that will result from the support requested. Attach as an Appendix item a draft Specific Aims page (or the equivalent, if submitted to an agency other than the NIH or AHRQ).
 - The intended grant submission date must be specified.
 - If the planned grant submission is in response to a specific funding opportunity announcement, include the name (such as title and reference number for NIH FOAs) and URL for the funding opportunity announcement. If the FOA is not readily available online, a copy must be included in the Appendix.
- Approach:
 - Describe the specific activities to be conducted under this Project
 - If the planned grant submission is a resubmission of a previously reviewed application, describe how the activities respond to previous critiques and strengthen the application.
- **The Research Plan must also include a Draft Specific Aims Page for planned R01-type application**
 - This should be included on its own page, ordered to follow the end of the Research Strategy Section.
 - Space on this page cannot be used to provide additional research strategy for the Opportunity Fund and circumvent the page limitation for the Research Strategy Section noted above.
 - It is recognized that the aims may be modified and this is a draft only. However, articulation of aims, even if vague or not finalized, demonstrates likelihood of achieving grant submission.
- **References Cited:** Limited to no more than two pages. Only include relevant citations that are cited in the application; do not prepare an exhaustive literature review. This should include no more than a dozen or so key references.
- For projects that include human subjects/participants, the following sections must be included:
 - **Protection of Human Subjects**
 - **Inclusion of women, minorities, and children**
 - **Targeted/Planned Enrollment Table.** If study participants will be included from more than one institution, present only one combined table. If numbers are not known, provide an estimate of anticipated or required numbers, and so indicate.

Be concise in these descriptions.

Note that this also applies to studies that are based on electronic or medical record data only with no planned participant contact, as those data are derived from human subjects:

- Include other PHS398 sections, such as use of vertebrate animals or special agents only if relevant to the application. Projects are limited to Population Sciences projects conducted in the CRN setting.

- List all participating institutions and the PI for each participating institution under **Consortium/Contractual Arrangements**.
 - If the Principal Investigator does not have a primary appointment at a CRN (including affiliates) Site, a **letter of support** from a co-investigator at each participating CRN (or affiliate) Site indicating agreement to participate in the proposed Project must be included.
 - In the rare instance in which the Principal Investigator holds a joint or adjunct but not primary appointment at a CRN or affiliate Site, but can submit grant applications from the CRN Site, a letter of support from a collaborating CRN or affiliate Site co-investigator is not required. However, a **brief note** from the Research Director or other appropriate official of the CRN Site must be included indicating agreement that the application may be submitted by the Principal Investigator. A copy of an email message to that effect is sufficient.
- **Multiple PI Plan**.
 - It is not expected that Projects will have multiple PIs; however, neither is this prohibited.
 - A rationale must be presented if more than one PI is designated.
 - Note that PI designation and receipt of an Opportunity Fund Project is not tracked in NIH RePORTER.
- A **Resource Sharing Plan** is not required.
- The following **Appendices** are or may be **required**:
 - If you are requesting support for activities that will facilitate response to a funding opportunity announcement such as an RFA, include the name of the FOA and URL pointing to the FOA in the Research Plan above. If a URL is not available, a copy of the funding opportunity announcement must be included.
 - If you are requesting support for activities that will facilitate response to an upcoming funding opportunity announcement, and the FOA has not yet been released, provide other documentation that the FOA will in fact be released in the near future, with an approximate submission due date.
 - If you are requesting support for activities to enhance likelihood of funding for resubmission of a previously-submitted application:
 - A copy of the previously-submitted grant application (principal text sections only, e.g., for NIH applications, the Abstract, Specific Aims, Research Plan, Human Subjects, and References sections)
 - A copy of the reviewer comments (“summary statement”) from the previous submission;
 - Other **Appendices** may be included, but please be parsimonious in their number and length, and limit only to those that are relevant for review of the Opportunity Fund application. Appendices cannot be used to circumvent the page limitation noted above.

Summary of Key Aspects for Preparation of Applications for the CRN Opportunity Fund

Application Section	Summary of Instructions
OVERALL	
Formatting	<ul style="list-style-type: none"> • Use PHS398 forms. They can be found here: http://grants.nih.gov/grants/funding/phs398/phs398.html • In general, follow NIH formatting requirements.
Face Page	<ul style="list-style-type: none"> • Formal institutional approval may be required at the time of submission. As we plan to support any meritorious applications until funding is exhausted, inclusion of formal institutional signatures will expedite any necessary subcontracting processes for successful applications. • Otherwise, complete all components of the Face Page. <ul style="list-style-type: none"> ○ Insert “CRN Opportunity Fund Program” under “RESPONSE TO SPECIFIC REQUEST FOR APPLICATIONS OR PROGRAM ANNOUNCEMENT OR SOLICITATION.” There is no number for this funding opportunity.
Budget	<ul style="list-style-type: none"> • Detailed Budgets and budget justifications must be submitted. • Total direct costs cannot exceed \$25,000. • Opportunity Fund Applications with a focus on convening a planning meeting are limited to \$10,000 in Direct Costs. • Include separate detailed budgets and budget justifications for each participating institution. • Include the sum of participating institution budgets (excluding the lead institution) on the lead institution’s budget under “Consortium/Contractual Costs” • As Projects will be funded as separate subcontracts from KPNC/KFRI to each participating institution, Indirect (F&A) costs for the lead institution are not allowed for consortium institution budgets. • Apply your Federally-approved Indirect (F&A) costs to your appropriate base to arrive at the total budget.
RESEARCH PLAN	
Page Limitations	<ul style="list-style-type: none"> • Specific Aims are to be included in the Research Strategy and are not required as a separate 1-page section. • The Combined Page Limitation for the Specific Aims plus Research Strategy Sections is 3 (three) pages total. • Draft Specific Aims for the planned R01-type application must be included and are limited to 1 separate page. • References Cited should be no more than 2 separate pages.
Formatting	<ul style="list-style-type: none"> • Text must be Arial typeface, font size no smaller than 11 point. • Tables and Figures must have a font size no smaller than 9 point. • Line spacing must be no smaller than single spacing. • Character Spacing must be normal and not condensed. • Margins must be at least 0.5 inches.

Application Section	Summary of Instructions
<p>Specific Aims and Research Strategy (two pages total)</p>	<ul style="list-style-type: none"> • Organize this Section as described above as: <ul style="list-style-type: none"> ○ Specific Aims/Objectives <ul style="list-style-type: none"> ▪ Outline the main objectives of the planned Project ○ Significance <ul style="list-style-type: none"> ▪ Describe in no more than one paragraph how the planned activities will support the planned R01-type application ○ Innovation <ul style="list-style-type: none"> ▪ Briefly describe in no more than one paragraph the innovation of the planned R01-type application ○ Planned R01-type Application <ul style="list-style-type: none"> ▪ Applications must specifically outline the planned grant application(s) that will benefit from the support requested. ▪ The planned submission due date must be specified. ▪ If the submission is in response to a funding opportunity announcement, the name of the FOA and a URL, if available, must be included. ○ Approach <ul style="list-style-type: none"> ▪ Describe the specific activities to be conducted under this Project. ▪ If the planned R01-type application is a resubmission, describe how the activities address specific critiques or otherwise strengthen the application.
<p>Specific Aims for Planned R01-type Application (one page total)</p>	<ul style="list-style-type: none"> • Limit to no more than one page. Include after the Research Strategy a draft Specific Aims for the planned R01-type application (or equivalent for non-NIH funding agencies). • It is recognized that this is a DRAFT and that there may be modifications in the aims when the grant is actually submitted.
<p>References Cited (two pages total)</p>	<ul style="list-style-type: none"> • Limit to no more than two pages. This should not be an exhaustive literature search. Include only citations referenced in the proposal.
<p>Human Subjects</p>	<ul style="list-style-type: none"> • If human subjects are involved in Project activities, include the following sections: <ul style="list-style-type: none"> ○ Protection of Human Subjects ○ Inclusion of Women, Minorities, Children ○ Targeted/Planned Enrollment Table: <ul style="list-style-type: none"> ▪ Include one combined Table if there is more than one institution contributing human subjects. ▪ Provide your best estimate if precise numbers are not available. • Human subjects are involved even if the Project is focused on electronic data only with no direct participant contact. • If no human subjects are involved in Project activities, state that this is so in this section.

Application Section	Summary of Instructions
Consortium/Contractual Arrangements	<ul style="list-style-type: none"> • If the Principal Investigator is not at a CRN or affiliate Site, a letter of support from a co-investigator who has a primary affiliation at a CRN or affiliate Site must be included. • In the rare instances where the PI may have a joint, adjunct or similar appointment but not a primary appointment at a CRN or affiliate Site and also has the privilege of submitting grant applications that originate from that Site, a brief note from the Site Research Director indicating support for submission of the application must be included.
Appendices	<ul style="list-style-type: none"> • Limit appendix materials to those that are relevant for evaluating the proposal. • Appendices cannot be used to circumvent page limitations. • May be required: If the planned R01-type application is in response to a specific funding opportunity announcement, include the name of the FOA and the URL in the body of the Research Plan. If a URL is not available, a copy of the FOA must be included.

Review Process

All steps in the process for review of applications for Opportunity Fund Projects will be conducted via email, teleconference, and other distance means of communication.

Up to four reviewers will be selected for each application, consisting of at least one scientist from a CRN or affiliate Site, at least one content specialist whose expertise matches that of the proposal, and potentially including a scientist from the NCI. Reviewers will be selected by the CRN Coordinating Center, in consultation with the CRN Executive Committee. Reviewers will be selected to avoid conflicts of interest as defined below. Applications will be considered based on the criteria noted in the Call for Applications.

Individual reviews will be conducted based on the evaluation criteria and the numerical scale used for NIH reviews, with scores ranging from 1 to 9, with a 1 being reserved for the most highly meritorious applications. Reviews will be compiled and summarized by the CRN Coordinating Center, highlighting the key strengths and weaknesses of each application. The bottom line will be a recommendation for or against funding. If there are discrepancies among the reviewers in this recommendation, these will be reconciled among the reviewers or by the CRN Executive Committee.

The reviewer comments, rankings, any related materials, and recommendations for funding will be presented for discussion on a monthly basis by the CRN Steering Committee, which will make the final decisions regarding funding of applications.

If the application is time-sensitive (e.g., related to an approaching submission deadline), an expedited review process in which the above steps are conducted in rapid sequence will be implemented.

Conflicts of Interest

All steps in the review process will be conducted to minimize conflicts of interest or appearance of conflicts to the extent possible. Given the nature of this program, however, and the fact that our aim is to support research in the CRN setting, it is highly likely that one or more members of the CRN Steering Committee—the final decision-making body regarding funding of applications—will have at least an institutional conflict with any given Project application.

Initial reviewers of Opportunity Fund Project applications, on which the final decisions are based, will be selected to be free of conflicts per NIH guidance (e.g., current or recent—within the past three years—collaborations with key personnel, employment at or seeking employment at applicant institutions). Initial reviewers will be required to certify that they did not review an application on which they have a conflict of interest, and members of the Steering Committees will be required to certify that they were not involved in discussions of any applications on which they have a conflict.



As funding decisions will be made on a per-application basis, Steering Committee members with a conflict of interest because of personal or institutional involvement in the application will recuse themselves and not participate in funding decisions for that application, but will not be required to absent themselves from the overall discussion of applications or the processes for deciding on funding decisions.



GENERAL GUIDANCE

Clarification of the intent of the Opportunity Fund:

- The Opportunity Fund is to fund activities that directly support the submission of an R01 or similar grant application, and to strengthen the likelihood of a positive review. Its purpose is not to determine feasibility of a possible R01 application. That is, every awarded Opportunity Fund project should result directly in one or more R01 or similar grant application.
- Any qualified investigator – that is, employed by or affiliated with an institution that can receive NIH grants – is eligible to apply for an Opportunity Fund project.
- The Opportunity Fund is not solely for young investigators such as CRN Scholars.
- The application must include a clear timeline for submission, including a clear target submission date, for the R01 or similar application, and a draft Specific Aims. Hence, the eventual R01 must be at least at that stage of development.
- Along those lines, if the applicant is not prepared to submit an R01 application that builds on Opportunity Fund activities within approximately one calendar year – and presumably earlier - then this is not an appropriate time to be submitting an application for this Opportunity. For example, for Opportunity Fund applications submitted in December, 2015, it is expected that plans are in place for submission of an R01 application no later than October 5, 2016 (or November 5, 2016 for a resubmission).
- The Opportunity Fund is to support activities that will enhance the likelihood of funding the eventual application. The range of activities is broad, as the Call makes clear - funding qualitative data collection, supporting a meeting of people, etc. But again, these activities are in service of the R01 application that is already being planned.

Regarding funding:

- If the Opportunity Fund is to bring people together to meet to respond to a Funding Opportunity or to prepare for an R01 submission, then travel expenses will be supported directly from KPNC (the prime institution for the NCI CRN grant). Subcontracts will not be modified or issued to institutions from which participating investigators may be employed.
- We can modify current infrastructure-related subcontracts to include Opportunity Fund dollars, as the proposed use falls under the umbrella of infrastructure activities. Note that we cannot modify Pilot Project or Scholar awards for this purpose, as those support specific activities.
- If you or someone you know does submit an Opportunity Fund application, please make certain that the budget is split into those dollars that can and will be spent in the current fiscal year, and those that will be spent later (if any). The fiscal year for CRN4 ends on August 31 for each year of the grant period through 2017.
- Opportunity Fund dollars should not be used to support the actual writing of grant applications. NIH grant funds are not used to write applications for other NIH grants. Thus, for example, you cannot ask for FTE to support an investigator to write the R01 application.

GENERAL QUESTIONS

1. *What are the CRN and affiliate Sites?*

The CRN and affiliate Sites and their research centers can be found on our [Participating Health Plans and Research Center Sites](#) page.

2. *What are the CRN Scientific Working Groups?*

The CRN Scientific Working Groups promote research ideas by leading activities in the following areas:

- Prevention & Screening
- Epidemiology of Prognosis & Outcomes
- Health Care Quality & Cost
- Communication & Dissemination

In addition, projects that build upon or enhance informatics resources are of interest. For further information, see our page on [CRN Scientific Working Groups](#).

3. *What if I'm not a CRN investigator (i.e., I do not have a primary research appointment at a CRN or affiliate Site)?*

The **Opportunity Fund Program** is open to investigators at any qualified research organization (e.g., that has a Federal-wide assurance number and is eligible to receive funds from the NIH). However, if you do not have a primary appointment at a CRN or affiliate Site, your application must include a co-investigator from a CRN or affiliate Site. Any research conducted within the CRN requires the scientific involvement of investigators at participating CRN or affiliate Sites.

4. *If I am not at a CRN or affiliate Site, how do I establish collaborations with a CRN investigator?*

If you have worked previously with a researcher at a CRN or affiliate Site, you can work with that individual to identify an appropriate co-investigator or to guide your research ideas. You can also contact the CRN Coordinating Center at cancer-research-network@kp.org. If so, please provide a brief description of your Project idea, and we will help identify appropriate co-investigators.

5. *How do I know if my proposal is a good match for the CRN?*

While there are no magic formulas for determining whether a research idea is a good fit for the CRN, the scope of work that we encourage falls broadly under the rubric of population sciences cancer research conducted in the integrated health care settings of the CRN. All Opportunity Fund Project applications must focus on activities, broadly defined, that will support submission of R01-type grant applications. Commitment to submission of an R01-type application in a timely fashion is a key element.

6. *How can I determine if a project idea I have is feasible?*

Investigators not at a CRN or affiliate Site should work with your CRN-based collaborating investigator to explore feasibility, such as determining frequencies of events, or availability of specific types of data. If your CRN collaborating investigator is unable to provide this information, you may contact the CRN Coordinating Center to explore feasibility issues (cancer-research-network@kp.org).

Applications for activities that do not appear to be feasible will not be supported. The intent of this Call for Opportunity Fund Applications is to support activities that will support submission of a potentially-fundable R01 application.

7. *Is there a CRN Prep-to-research process for determining project feasibility?*

The CRN has a Prep-to-Research Process in place. If you are planning to submit an R01 or other grant and your request or project's preparatory work can be accomplished through this process, please submit a PTR form to cancer-research-network@kp.org. The completion of these requests is considered CRN infrastructure work and is of no cost to the investigator. [Prep-to-Research Form](#)

8. *The Opportunity Fund Project announcement states that the "work to be undertaken with Opportunity Fund Project funds need to be conducted in the CRN setting" or in the "CRN integrated health care setting." Does this mean that all data analysis needs to occur at a CRN Site or affiliate Site?*

No.

Analytic datasets may be created from data that are extracted from databases that are developed and maintained by each of the CRN research organizations. These analytic datasets may then be transferred to an investigator at an external institution. As with all research that involves human subjects, data transfers may occur provided IRB requirements are met (if appropriate) and relevant data use or transfer agreements are executed (also if appropriate). As the intent of this Call is to provide timely support of grant applications, data sharing should aim to include de-identified datasets only.

You may also conduct active data collection from focus groups, interviews, questionnaires, or other methods from people who receive health care at CRN institutions, or from providers or systems leaders depending on your research plans and interests. Data from direct data collection can also be transferred to an investigator at an external institution, with appropriate approvals and oversight.

In addition, Projects may include activities that are conducted at institutions other than the CRN or affiliated Sites. Examples of projects with activities outside the CRN setting that may be appropriate include, but are not limited to:

- Projects in which some study participants are enrolled from one or more CRN or affiliate Sites, while others are enrolled from other settings.

- Projects in which biospecimens have been or will be collected from members of CRN health plans, but are analyzed in laboratories elsewhere.
- Projects that compare aspects of care in the integrated health care settings of one or more CRN or affiliate Sites with fee-for-service or safety-net health care settings.
- Projects that translate or disseminate practices from CRN institutions to non-CRN institutions – or vice versa.

Because the intent of this program is to catalyze research projects that will lead to cancer research conducted in the CRN setting, and all projects must include some aspect of use of CRN resources, as previously noted, all projects must involve at least one CRN investigator.

9. *Why can't the CRN simply provide data that can be analyzed by researchers not affiliated with CRN institutions, such as is possible with datasets from NHANES or the SEER-Medicare linked datasets?*

The data that are available from CRN and affiliate Sites are derived from clinical and administrative databases that are collected and maintained by the non-profit integrated health care organizations with which CRN research organizations are affiliated. These are not normally considered public data, unlike data from NHANES or the SEER program. They may also have proprietary content. These data are made available by these health care organizations for public-domain research through grants such as the CRN and other funded research projects.

In addition, researchers based at CRN institutions are stewards, not owners, of these data. Thus they have the responsibility to ensure that these data are used for appropriate purposes and are also interpreted appropriately. Under appropriate IRB approvals and data use agreements (when necessary), these data can be shared for defined research purposes. These considerations apply even for de-identified or anonymized datasets.

ADMINISTRATIVE OR PROCESS QUESTIONS

10. *How many projects are you funding in this round?*

The specific number of projects will depend on the number of applications received and their budget requests. With a rolling submission date, we will likely fund all meritorious applications until funds are exhausted. As budgets requests are likely to vary substantially, we cannot predict the number of projects we will support. The total amount of funding available to support this program will vary from year-to-year.

11. *How long is the typical project?*

These funds are intended for activities that directly support submission of an R01-type application, and are thus expected to support activities that can be completed in no more than several months. Regardless, all projects must be completed within one year. These projects are not renewable.

12. *What is an “R01-type” grant application?*

The CRN is interested in facilitating research activities that are supported by grants such as investigator-initiated research applications funded by the NIH – the R01. However, there are other funding mechanisms supported by the NIH that are also of interest, such as investigator-initiated program project grants (P01s), or grants funded through other mechanisms (e.g., cooperative agreements such as U01s).

In addition, we recognize that other funding agencies provide support for R01-type applications. We welcome applications that are aimed at specific funding opportunities and submission deadlines for these other funding agencies. For the purposes of this program, we rely on the list of funding agencies maintained by the NCI Cancer Centers Program, which is available [here](#).

Note that the Opportunity Fund will not support activities for which the planned outcome is submission of an R03-type (“pilot project”) application or career development award.

13. *What is expected of those who receive funding from the Opportunity Fund Program?*

The CRN will award funds to the applicants who plan to submit an R01-type grant application. All recipients of Opportunity Funds are expected to submit an R01-type grant application at the earliest reasonable opportunity.

We anticipate that Projects will lead to full grant proposals, but understand that some Project work may determine that further development in an area is not feasible, even though feasibility *per se* is not the focus of Opportunity Fund projects. In those cases, clear justification of why an R01-type grant application will not be submitted must be provided to the CRN Coordinating Center.

Opportunity Fund activities are considered unique projects and do not fall under required infrastructure activities under CRN4. PIs will be required to submit separate progress reports for the annual CRN Progress Report.

14. *What type of final report is required upon completion of the study?*

The PIs of all projects that are funded will be required to provide a short summary of activities to be included in the CRN Annual Progress Report. This will be due no later than June 15 within the CRN Fiscal Year (Sept 1-Aug 31) that the project was funded. A complete copy of the R01-type grant application that was facilitated by these

Opportunity Funds must be submitted to the CRN Coordinating Center, and will function as a Final Report. This copy must be submitted within one month after submission to the funding agency. Any presentations or manuscripts (submitted or published) that have resulted from this work should also be submitted.

15. *Is it possible under this funding mechanism to submit a grant with two principal investigators?*
As with NIH applications, you may name multiple PIs. If so, you must include a rationale for why you need more than one PI, and the role of each named individual PI.
16. *I am planning to submit a request to support activities in response to an RFA. Are there any special requirements?*
Please include either a copy of the funding announcement, or a link to the URL for the funding announcement. If the submission deadline is imminent, the review and decision on funding will be made as expeditiously as possible. For further information, please see the Opportunity Funds Application Instructions.
17. *I am planning to submit a request to support activities for resubmission of a previously-reviewed grant application. Are there any special requirements?*
Please include a copy of the previous application's reviewer critique (e.g., NIH summary statement). Also, you must point to the specific comments in the summary statement that will be addressed by the activities for which you request support. As with all Opportunity Fund applications in response to this Call for Applications, you must indicate the target submission deadline. For further information, please see the Opportunity Funds Application Instructions.

BUDGET QUESTIONS

18. *Is there a cap on budget requests?*
The direct costs for the budget should not exceed \$25,000. If an applicant believes that she or he would require a larger level funding for activities to support the planned R01-type application, this should be discussed with the CRN Coordinating Center prior to preparation of an application for an Opportunity Fund project. The \$25,000 cap is the Direct Costs for all participating institutions. Opportunity Fund Applications with a focus on convening a planning meeting are limited to \$10,000 in Direct Costs.
19. *What about indirect (F&A) charges?*
All budgets should include indirect costs using the appropriate Federally-approved indirect (F&A) rate of the applicant institution(s).
20. *If I have more than one institution in my budget, should I include them as a subcontract from my (lead) institution's budget, or should each institution have a subcontract from*

Kaiser Permanente Northern California (KPNC) / Kaiser Foundation Research Institute (KFRI), the CRN prime institution?

Funds for any institution participating in an awarded Opportunity Fund Project will be funded as a subcontract from KPNC / KFRI, even if your institution already has a subcontract with KFRI under the CRN U24 Grant. If multiple institutions will be submitting a single Opportunity Fund Project application together, separate detailed budgets will need to be submitted for each institution. An overall summary budget, as would ordinarily be submitted to the NIH, must also be included in the lead institution's budget. However, the lead applicant institution's F&A costs should not be applied to costs associated with collaborating institutions.

21. *Can you clarify whether indirect (F&A) costs are allowable on the indirect costs of the first \$25,000 of subcontracts?*

When creating a budget for an NIH-funded grant, for most institutions, the indirect costs on the first \$25,000 of subcontracts is considered a direct cost on the prime applicant's budget. As stated in NIH guidance

(http://grants.nih.gov/grants/developing_budget.htm):

"F&A costs for the first \$25,000 of each consortium (subcontract organization) may be included in the modified total direct cost base, when calculating the overall F&A rate, as long as your institution's negotiated F&A rate agreement does not express prohibit it."

However, because each successful Opportunity Fund Project applicant will be funded as a subcontract to the parent CRN award, there are no subcontracts to the prime applicant for a CRN Opportunity Fund Project. Thus, the prime applicant cannot include F&A costs on any portion of the budget for subcontract institutions.

To summarize:

- For a given Opportunity Fund Project, each participating institution's budget should include its appropriate full Federally-approved indirect rate.
- The lead applicant institution cannot charge F&A rates on any portion of any consortium institutions' budgets.
- The lead applicant will submit the total budget packet, including each institution's budget, as they would for a typical NIH application.

22. *Do I need to submit a checklist, as I would in a federal grant submission?*

Yes. A checklist is required for each participating institution.

23. *Can you provide more information about the subcontracting process?*

All institutions included in each Opportunity Fund Project will have a subcontract to KPNC (through KFRI). As an example: If you are the PI of the project and there are multiple institutions involved in the project, all institutions will have subcontracts to

KPNC, not to your institution. This holds even though all institutions will be providing the PI's institution with their budget information for a single submission.

If your institution *already* has a CRN subcontract with KPNC (through KFRI), we can modify infrastructure-related subcontracts to include Opportunity Fund dollars, as the proposed use falls under the umbrella of infrastructure activities. Note that we cannot modify Pilot Project or Scholar awards for this purpose, as those support specific activities. However, as noted above, Opportunity Fund activities are considered unique projects and do not fall under required infrastructure activities under CRN4. PIs will be required to submit separate progress reports for the annual CRN Progress Report.

If your institution is *not* a CRN Site or Affiliated Site and is participating in more than one Opportunity Fund Project and awarded for more than one, each project will be treated as a unique project and will therefore have separate subcontracts.

24. *Can my institution include a lower indirect than my institution's Federally-approved indirect rate?*

If your institution agrees, you can include an indirect rate that is less than your Federally-approved indirect rate. If you do so, as part of your budget justification, you must include documentation of your institution's usual Federal rate and the base upon which it is calculated. Also, include, from someone who can speak on behalf of your institution, a statement that the institution is willing to accept a grant at less than your Federally-approved rate and at the rate provided in the budget.

Please note: Even if your institution is willing to forgo the full rate and use a lower rate, your collaborating institutions may not be willing to do so for their portion of your overall budget. In addition, total direct costs are capped at \$25,000 for the Opportunity Fund project.

25. *Do I need to complete an NIH Targeted/Planned Enrollment Form even though my study does not include direct participant contact, but is a retrospective, medical record data only project?*

All Opportunity Fund Projects that involve human subjects require the submission of an NIH Targeted/Planned Enrollment Form, even for retrospective studies that include only electronic data or medical record review in which requirement for informed consent is waived. You should include this Form for the subjects in the study even if they are not officially "enrolling" as participants, as the NCI and reviewers will need to have an idea of the scope of the project. In addition, as with regular NIH applications, it is important to discuss inclusion of women, minorities, and children.

Please note that this form pertains only to activities conducted under the Opportunity Fund Project, and not to the planned R01-type application.



26. *Do I need IRB approval for my Opportunity Fund Project?*

You do not need IRB approval prior to submitting your Opportunity Fund Project application. Indeed, some or all of the activities that you plan may not be “research” per se. Such activities might include convening an in-person meeting to plan for submission of an application, or testing the validity of planned laboratory assays. In addition, many activities may be considered “preparatory to research” as they will be conducted to support a research application, and may thus not require IRB approval.

However, in general, activities that will involve direct contact of participants, such as for participation in focus groups or completion of surveys in which respondents are identifiable, including in Project activities, will require IRB approval. This may include data-only projects with no participant contact that use data, such as from electronic health records, collected from human subjects. If required, approval must be obtained prior to any research activities under this funding. You may want to take institutional IRB timelines into account as you determine whether to request IRB approval prior to notification of successful receipt of a CRN Opportunity Fund Project.

Depending on the nature of the project, you may also need to execute data use or materials and data transfer agreements, which should be considered in your timeline.

27. *Do I need formal institutional signatures to submit a CRN Opportunity Fund Project application?*

If your application will require creation of a subcontract from the CRN’s prime grant, the application will require formal institutional signatures. In addition, your institution may require that budget preparation and estimates, in order to be as accurate as possible, also require institutional approvals. Regardless, we strongly encourage applicants to review their projected budgets and activities with their institutional grants and contracts offices prior to submission, to ensure accuracy and compliance with any relevant institutional or other requirements.

28. *What is the source of funds for the Opportunity Fund Projects?*

The CRN is funded as a research resources cooperative agreement by the National Cancer Institute; the grant number is U24 CA171524 (Lawrence H. Kushi, Principal Investigator). The Developmental & Pilot Projects Program is one of the activities supported by this grant, and the Opportunity Fund is one of the mechanisms through which these funds are disbursed. As described above, Opportunity Fund Projects funded under this program will be funded as subcontracts from the prime recipient of this U24 grant from the NCI (Kaiser Permanente Northern California / Kaiser Foundation Research Institute) to the institutions that compete successfully for Opportunity Funds.

29. *What if my question is not answered here?*

Please speak with your CRN collaborating investigator, or contact the CRN Coordinating Center at cancer-research-network@kp.org.