CRN

CANCER RESEARCH NETWORK

2014

Pilot Project Announcement Materials

1. Call for Applications
2. Application Instructions
3. Review Process
4. Frequently Asked Questions

CRN
CANCER RESEARCH NETWORK

CRN Developmental & Pilot Projects Program
Call for Pilot Project Applications

Overview

The Cancer Research Network (CRN) invites applications for Pilot Projects that will lead to further research addressing issues that can decrease the burden of cancer. 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/HMO Research Network setting is ineligible.

The expectation is that the money invested in Pilot Projects will lead to fundable research applications or proposals. Pilot Projects must clearly indicate plans for conducting work that would result in an eventual application for funding, such as for an R01 or other research award, including career development awards, from the NIH or other funding agencies with a competitive peer-review process.

Research Focus

Projects are invited that address questions that fall under the CRN scientific areas of 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. Research questions that also address Informatics capabilities or improvement of CRN-based data or other resources are also invited.

In particular, the CRN invites pilot projects that address the following topic areas:

Prevention & Screening

- What aspects of shared-decision making for cancer screening result in optimal screening rates?
- How are screening and follow-up services for lung cancer being implemented, and what are the reasons for variation (if any) in such implementation? What are the predictors and outcomes of surveillance and follow-up of screening for lung cancer?
- How can clinical biospecimens (e.g., biopsies resulting from cancer screening) or other information be leveraged for use in early detection of cancer, and for differentiating indolent from progressive disease?

Epidemiology of Prognosis & Outcomes

- Can patient-reported outcomes be captured reliably in electronic medical records, and can such data be used to examine impact of cancer care?
- What impact do behavioral factors (e.g., tobacco use, physical activity, diet, supplement use) and changes in these factors have on outcomes in cancer survivors?
- What approaches may best reliably and efficiently identify recurrences for cancers other than breast cancer?

Health Care Quality & Cost

- What are the determinants, outcomes, and costs associated with hospitalization, lengths of stay, readmission, and post-hospital utilization for cancer patients?
- What proportion of cancer patients die in the hospital or soon after discharge, and what factors predict such mortality?
- What is the variation in use of advanced digital imaging procedures prior to initiation of definitive therapy, by or for a given type of cancer patient, provider, facility, insurance coverage or health system, and what are the predictors of use of these procedures?

Communication & Dissemination

- How do patients or health plan members, with or without cancer, understand cancer risk? Does better understanding of the risks and uncertainties associated with cancer and its screening or treatment decisions contribute to improved care and cost savings?
- How do health plans/health care organizations communicate with patients about cancer-related risk? And what health care organization-generated messages about risk are effective, and under what circumstances, in improving patient knowledge and understanding of cancer-related risk?
- What potential outcomes of physician-patient communication over the course of cancer care are most important to various stakeholders, and how might variations in these perceived outcomes impact care?
- How do clinicians or healthcare organizations respond to research findings and guidelines and integrate them into delivery processes?

Projects that address other topic areas are also invited. We recognize that there are many important research questions that may be addressed in the CRN context, and the questions noted above capture only a small portion of those that may be considered innovative and of high priority.

We recognize that a Pilot Project itself is unlikely to be able to provide definitive findings related to any of the questions noted above. However, we encourage Pilot Projects that conduct preliminary or feasibility work that can lead to research projects that address these questions with subsequent R01-type 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 applications and be funded under this program. Examples of qualified research institutions 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 pilot 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.

In order to ensure broad representation of research funded through this program, **it is unlikely that more than one Pilot Project from any lead institution will be funded**.

Pilot Projects Evaluation Criteria

Applications will be judged by the following criteria:

- Potential for leading to a fundable R01-type research grant application;
- Significance, Innovation, and Approach, per NIH review criteria;
- Scientific focus in one of the four CRN strategic areas as represented by the CRN Scientific Working Groups, or Informatics.
- Addressing one of the research topic areas described in this Call for Applications under "Research Focus."

In addition, if there are more meritorious applications than can be supported, funding decisions will also consider the following:

- Involvement of or lead by a junior investigator;
- Leverages unique features of the CRN and HMO setting;
- Inclusion of collaboration with a research partner institution outside CRN and affiliated sites;
- Distribution of funded projects among the CRN Scientific Working Group areas.

Funding

Approximately $325,000 is available to fund CRN Developmental and Pilot Projects in this round of funding. We expect to fund four or five total projects, including Development Projects (see separate announcement). The number of projects funded assumes receipt of meritorious applications. Projects should have budgets of no more than $75,000 in total costs (including direct and indirect costs); any exceptions must be discussed before submission with the CRN Principal Investigator, Dr. Lawrence Kushi, and the CRN Executive Committee.

This program is supported by funds awarded to the CRN by the National Cancer Institute (NCI). Any Pilot Projects that are awarded are subject to all the regulations that pertain to receipt of NIH funds, including IRB approvals prior to initiation of research activities under the Pilot Project.

Pilot Projects are one-year, non-renewable grants. Projects will be funded as subcontracts to the applicant organization(s) from Kaiser Permanente Northern California (KPNC) through the Kaiser Foundation Research Institute (KFRI). Although subcontracts for the Pilot 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, the CRN Pilot Project budget year that pertains to this Call for Applications is August 1, 2014 – July 31, 2015.

2014 Application Process

Required Letter of Intent – Due Monday, March 3, 2014, 5 pm Pacific Time
A required letter of intent (LOI) must be submitted to the CRN Coordinating Center. Letters of Intent will be reviewed by CRN personnel for the principal criteria provided above, and select applicants will then be invited to submit a full Pilot Project application. We expect to invite no more than 40 applicants to submit full applications. Further details regarding the content and format of the required Letter of Intent are provided in the Application Instructions.

Full Pilot Project Application – Due Friday, May 16, 2014, 5 pm Pacific Time
Full Pilot Project Applications will be accepted only from investigators who have been invited to submit an application after CRN review of the required Letter of Intent. Unsolicited full Pilot Project applications will not be reviewed and are ineligible for funding.

Further details regarding the content and format of the full Pilot Project Application are provided in the Application Instructions.

2014 Application Schedule

Tuesday, February 11 .....Informational Webinar and Q&A for CRN Developmental and Pilot Program – Letters of Intent phase, 10 am to 11:30 am Pacific Time. Contact the CRN Coordinating Center for webinar information.

Tuesday, February 25 .....Webinar with presentations by currently-funded (2013) Pilot Project investigators, 9 am to 11 am Pacific Time. While not specifically for this purpose, this webinar can provide potential applicants with examples of successfully-funded CRN Pilot Projects. Contact the CRN Coordinating Center for webinar information.

Monday, March 3 .....Letters of Intent due at CRN Coordinating Center, by 5 pm Pacific Time.

By Monday, March 17 .....Peer review of Letters of Intent completed.

By Monday, March 24 ....Notification to Principal Investigator of invitation to submit Full Pilot Project Application.

Monday, April 14.....Informational Webinar and Q&A for CRN Developmental and Pilot Program – Full Application phase, 12 noon to 2 pm Pacific Time. Webinar information will be provided to all applicants who are invited to submit a Full Application.

Friday, May 16 .....Full Pilot Project Applications and budgets due at CRN Coordinating Center by 5 pm Pacific Time.

By Friday, June 6.....Initial peer review of applications completed.
Friday, June 20 .....Review Committee meets to rank and recommend projects for funding.
Wednesday, June 25 .....CRN Steering Committee selects projects for funding.
By Friday, June 27.....Applicants notified of funding decision.
By July 1 .....Draft subcontract(s) initiated with successful applicant organization(s). Successful applicant organizations initiate IRB applications.
August 1 .....Pilot Project Start Date; actual completion of fully-executed subcontract and ability to invoice KPNC/KFRI will depend on institutional processes.

Review Process

Please see this page on our website for a summary of the Review Process.

Questions during Preparation of Proposals

Two informational Q&A type webinars have been scheduled prior to the submission deadlines for Letters of Intent and Full Applications. The dates and times for these webinars are noted in the 2014 Application Schedule above.

We have also prepared a list of frequently-asked questions on the Pilot & Developmental Projects Program.

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.

CRN Developmental & Pilot Projects Program
Application Instructions

Required Letter of Intent

Due Monday, March 3, 5:00 pm Pacific Time to cancer-research-network@kp.org

The required Letter of Intent may be submitted as MS Word documents or as PDF documents; a single compiled PDF document is preferred.

The required Letter of Intent must include the following:

- A **cover page** that provides the following information:
  - Title of Application
  - Name and affiliation of Principal Investigator
  - Names and affiliations of any co-investigators
  - For Pilot Projects, the CRN Scientific Working Group(s) (SWGs) that are relevant for the proposed project
  - For Pilot Projects, the Research Focus question(s) that is addressed at least in part by the proposed project, if relevant
  - For Developmental Projects, which component of the CRN – SWGs, Informatics Core, Outreach & Collaborations Core, Scholars Program – the project will enhance.
- A **one-page (or less) description** of the proposed Developmental or Pilot Project.
  - Please organize the one-page description in the following manner, similar to a structured abstract:
    - Rationale: A brief rationale, background, or context statement, including its relevance to the CRN research setting and SWG emphasis areas;
    - Objectives: A statement of the Developmental or Pilot Project Specific Aims or Objectives;
    - Approach: A clear description of proposed methods;
    - Anticipated Outcomes: A statement of anticipated findings or outcomes of the Developmental or Pilot Project;
    - Future Directions:
      - For *Pilot Projects*, how this work will result in or enhance preparation of a potentially fundable R01 or similar application;
      - For *Developmental Projects*, how this work will enhance cancer research resources and ability to conduct cancer research in the CRN setting.
  - This one-page description must use no smaller than 1 inch margins (headers and footers may be outside this margin). Text must use Arial typeface with a font size of no smaller than 11 point. Line spacing must be set at single or wider spacing.
- **NIH-format biosketches** of no more than four pages each for the Principal Investigator and co-investigators
- For Pilot Project applications, if the Principal Investigator does not have a primary appointment at a CRN Site, **a letter or statement of support** from a co-investigator at a CRN Site indicating agreement to participate in the proposed Pilot Project must be provided. A copy of an email message so indicating can suffice.

- For Developmental Project applications, the Principal Investigator must have a primary or other appointment at a CRN or affiliate Site, and ability to submit applications from that Site.
- Lastly, please complete the online Pilot Projects Intake form. This replicates the information requested on the cover page and will be used for administrative purposes.

Full Pilot & Developmental Project Application

Due Friday, May 16, 5:00 pm Pacific Time to cancer-research-network@kp.org
The application must be submitted using **PHS398 forms** linked to here on the NIH website.

Formatting Requirements: The Full Developmental or Pilot Project 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 full Developmental or Pilot Project application may be submitted as MS Word documents or as PDF documents; 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 prepared in the case of successful funding.

The Developmental or Pilot Project application should include the following:

- The **Face Page** (PHS398 Form Page 1) including its required components, updating the information provided previously in the Letter of Intent:
  - Title of Application.
  - Name and affiliation of Principal Investigator.
  - Formal institutional approval and signatures are not required.
  - A Face Page should be included for all collaborating organizations for each Project application.
- **Description, Project/Performance Sites, Key Personnel** (PHS398 Form Page 2) should include:
  - Abstract of Developmental or Pilot Project.
  - For Pilot Projects, as the last sentence of the Abstract, indicate which CRN Scientific Working Group(s) (SWG(s)) are relevant to the proposed project. Include a sentence such as: "This project fits the interests of the CRN xyz Scientific Working Group."
  - For Developmental Projects, as the last sentence of the Abstract, indicate which CRN SWG, Informatics Core, Outreach & Collaborations Core, Scholars Program, or other aspect of

CRN activities the project will enhance or support. Include a sentence such as: "This project will enhance the activities of xyz of the CRN."
  - Names, roles on project, 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.
- 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 Developmental or Pilot Project.
  - The PI institution budget should also include the compiled summary budget, with 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 one year only, 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 four pages for any individual.
- **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 **combined page limitation** for the Specific Aims *plus* Research Strategy Sections is **five pages total**. This differs from general NIH application instructions.
- The **Specific Aims** Section should be less than **one** page.
- The **Research Strategy** Section should be organized in the following sequence:
  - Significance
  - Innovation
  - Approach
  - Future Directions:
    - Pilot Project applications must specifically outline the planned future grant application(s) that may result from the work in the Pilot Project.
    - Developmental Project applications should indicate potential plans for dissemination and implementation of resources throughout the CRN.
- **References Cited**: Only include relevant citations that are cited in the application; do not prepare an exhaustive literature review. This should be no more than one or two pages.
- For projects, including Developmental 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. Recall that 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**.
  - For Pilot Projects, 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 Pilot 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.
  - For Developmental Projects, the Principal Investigator must have an appointment at a CRN or affiliate Site and the ability to submit grant applications from that Site. As above, if the PI holds a joint or adjunct but not primary appointment at a CRN or affiliate site, a **brief note** from the Research Director or other appropriate official of that institution must be included indicating agreement that the application may be submitted by the PI.
- **Multiple PI Plan**.
  - It is not expected that Developmental or Pilot Projects will have multiple PIs; however, neither is this prohibited.
  - A strong rationale must be presented if more than one PI is designated.
  - Note that PI designation and receipt of the Developmental or Pilot Project will not be tracked in NIH RePORTER.
- A **Resource Sharing Plan** is not required.
- While **Appendices** may be included, please be parsimonious in the number and length, and limit only to those that are relevant for review of the application. Appendices cannot be used to circumvent the page limitation noted above.

Summary of Key Aspects for Preparation of Full Applications for the CRN Developmental & Pilot Projects Program	
Application Section	**Summary of Instructions**
OVERALL	
Formatting	• 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	• Formal institutional approval not required at the time of submission. • Such approval will be required as part of the subcontracting process for successful applications. • Otherwise, complete all components of the Face Page. o Insert "**CRN 2014 Developmental & Pilot Projects Program**" under "RESPONSE TO SPECIFIC REQUEST FOR APPLICATIONS OR PROGRAM ANNOUNCEMENT OR SOLICITATION." There is no number for this funding opportunity.
Budget	• **Detailed Budgets and budget justifications** must be submitted. • **The total budget, including F&A costs, cannot exceed $75,000.** • 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.
RESEARCH PLAN	
Page Limitations	• **The Combined Page Limitation for the Specific Aims plus Research Strategy Sections is 5 (five) pages total.** • **Specific Aims should be no more than 1 page.** • **References Cited should be no more than 2 pages.**
Formatting	• **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**.

Summary of Key Aspects for Preparation of Full Applications for the CRN Developmental & Pilot Projects Program	
Application Section	**Summary of Instructions**
Specific Aims and Research Strategy	• Organize this Section per NIH guidance as: o **Specific Aims** (no more than one page) o **Significance** o **Innovation** o **Approach** o **Future Directions** ▪ **For Pilot Projects**: Describe the planned R01 or similar application(s) that will result from the Pilot Project ▪ **For Developmental Projects**: Describe how the planned activities will enhance cancer research in the CRN setting, and how activities will be disseminated throughout the CRN.
References Cited	• **Limit to no more than two pages**. This should not be an exhaustive literature search. Include only citations referenced in the proposal.
Human Subjects	• If human subjects are involved in the Developmental or Pilot Projects application, include the following sections: o **Protection of Human Subjects** o **Inclusion of Women, Minorities, Children** o **Targeted/Planned Enrollment Table**: ▪ 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.
Consortium/Contractual Arrangements	• 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	• Limit appendix materials to those that are relevant for evaluating the proposal. • Appendices cannot be used to circumvent page limitations.

CRN Developmental & Pilot Projects Program
Application Review Process

Review Process

All steps in the review process will be conducted via email, teleconference, and other long-distance means of communication.

Required Letter of Intent

Each Letter of Intent will be screened initially by the CRN Coordinating Center for responsiveness to basic elements of this program (e.g., the Pilot Project involves population science research, the Pilot Project does not propose a basic science study, etc).

Assuming the Letter of Intent describes an appropriate project, it will be sent to a review committee of three individuals, selected based on the content of the Letter of Intent, familiarity with relevant work in the CRN, and to avoid conflicts of interest as defined below. If possible, at least one of the appropriate CRN Scientific Working Group(s) or Informatics Core co-leads will be included in this review. If possible, the review team will also include one individual from the National Cancer Institute. The Letters of Intent will be reviewed to determine whether the applicant should be invited to submit a full Developmental or Pilot Project Application, with specific attention to the overall criteria for funding of applications. The review committee or CRN Executive Committee members may choose to ask others to review the Letters of Intent, based on work load, expertise, and other considerations.

Reviewer recommendations will be compiled by the CRN Coordinating Center. Recommendations will be reviewed by the Coordinating Center and the CRN Executive Committee, who will determine which applicants to invite to submit full applications.

Full Pilot & Developmental Project Application

Three 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.

Reviews by individual reviewers will be conducted based on the evaluation criteria and the general approach 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. A Review Committee that consists of about half a dozen members, including, but not limited to, representatives from the NCI and the CRN Steering Committee, will review the compiled results. This Review Committee will then arrive at a ranking of Pilot Project applications, and recommendations for funding.

The complete reviewer rankings, summary reviews, related materials, and recommendations of the Review Committee will be made available to the CRN Steering Committee, which will make the final decisions regarding funding of applications.

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 and resource development in the CRN setting, it is highly likely that members of the CRN Steering Committee—the final decision-making body regarding funding of applications—will have an institutional conflict with at least one, if not more, Developmental or Pilot Project application/s.

Any individual with a conflict of interest while serving as a member of the Review Committee or Steering Committee will recuse themselves from discussion or voting on that specific application, but will not be required to absent themselves from the overall discussion of applications. Initial reviewers of Developmental or Pilot Projects, 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 Review and Steering Committees will be required to certify that they were not involved in discussions of any applications on which they have a conflict.

CRN
CANCER RESEARCH NETWORK

Call for Developmental & Pilot Projects
Frequently Asked Questions

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 **Pilot Projects 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. Please note that physicians practicing at one of the HMOs of the CRN must also find an investigator with a research appointment to collaborate with.

   For **Developmental Projects**, the Principal Investigator must be at a CRN or affiliate Site. This is required because the intent of this project is to support research that is conducted in the CRN setting or using CRN resources.

4. *If I am not a CRN investigator, can I submit a Letter of Intent if I do not have a co-investigator who is at a CRN or affiliate Site?*

   No. All applications, including the Letter of Intent, must identify an investigator who is at a CRN or affiliate Site, whether as the Principal or as a co-Investigator.

5. *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. Please provide a brief description of your pilot project idea, and we will help identify appropriate co-investigators.

6. *How do I know if my proposal is a good match for the CRN?*
   While there are no magic formulas for determining whether a Developmental or Pilot Project 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. In the 2014 Call for Applications, we highlight several questions that are of particular interest. Pilot Projects that plan preliminary or feasibility work to develop R01-type grant applications that address one or more of these questions are of particular interest. Again, project topics are not limited to those that are related to these questions. Follow the link to see a list of Pilot projects funded in 2013: http://crn.cancer.gov/dissemination/newsletters/2013julaug/#pilot

7. *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).

   It is not expected that all aspects of feasibility will have been worked out for your proposed Pilot or Developmental Project, or for the project that may result from the pilot work. Indeed, an objective of your Pilot or Developmental Project may be to establish feasibility of some key aspects of data availability or quality, recruitment, or other study design aspects. However, your application should include some basic information provided such as estimates of the numbers of study participants or events that may be of interest, or the potential availability of key data elements.

8. *The Pilot and Developmental Project announcements state that the "work to be undertaken with Developmental or Pilot 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 is 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).

   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, pilot 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 a fee-for-service or safety-net health care setting.
- 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 units 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 for public-domain research through grants such as the CRN and other funded research projects. However, 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, these data can be shared for defined research purposes.

ADMINISTRATIVE OR PROCESS QUESTIONS

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

While the specific number of projects will depend on the receipt of meritorious applications and their budget requests, we anticipate awarding four or five total awards. We anticipate that perhaps one of these projects will be a Developmental Project. The total amount of funding available to support this program is about $325,000 this year.

11. *How long is the typical project?*

These funds are intended for activities that can be completed in one year or less, and will be awarded as a one-year budget. These projects are not renewable.

12. *Why is the Letter of Intent required?*
    The Letter of Intent provides a mechanism by which initial review of potential applications can be accomplished using a relatively streamlined approach. This will ensure that Full Applications are aligned with the intent of the program.

13. *What is expected of those who receive funding from the Developmental & Pilot Projects Program?*
    The CRN will award funds to the applicants that appear to have the greatest chance of becoming full grant applications (for Pilot Projects) or have the greatest likelihood of enhancing CRN resources to support cancer research (for Developmental Projects), thereby building on the CRN's capabilities and scientific capital. In most cases, recipients of pilot funds are expected to submit a full grant proposal based on the completion of their pilot, at the earliest possible opportunity. We anticipate that most pilot projects will lead to full grant proposals, but understand that some pilot work may determine that further development in an area is not feasible.

14. *What type of final report is required upon completion of the study?*
    All PIs will be required to submit a status update no later than May 15, 2015. A final report must also be submitted by October 1, 2015. Any presentations, manuscripts (submitted or published), or grant applications (submitted or funded) that have resulted from this work must be submitted as part of the final report.

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. *Can the structure and aims of the pilot project be modified from what was originally proposed in the LOI?*
    Yes. We understand that after taking the budget into consideration, the aims may need to be modified in order to carry out a feasible work plan within the constraints of a $75,000 cap. If you make changes to your project that involve adding or subtracting institutions or researchers, please inform the Coordinating Center as this will help facilitate advance preparation for the review process. Such modifications may determine who can or cannot be a reviewer for your project.

BUDGET QUESTIONS

17. *Is there a cap on budget requests?*

The total budget, including direct and indirect (F&A) expenses for any single project, should not exceed $75,000. If an applicant believes that she or he has a meritorious idea that requires a somewhat larger budget, this should be discussed with the CRN PI as soon as possible.*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), for the budget year August 1, 2014 – July 31, 2015.

18. *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), for the budget year August 1, 2014 – July 31, 2015.

19. *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 Developmental or Pilot 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 Developmental or Pilot 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.

20. *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 pilot project applicant will be funded as a subcontract to the parent CRN award, there are no subcontracts to the prime applicant for a CRN Developmental or Pilot Project. Thus, the prime applicant cannot include F&A costs on any portion of the budget for subcontract institutions.

To summarize:

- For a given Developmental or Pilot Project, each participating institution's budget should include their appropriate full Federally-approved indirect rate.
- The lead applicant institution cannot charge F&A rates on any portion of any subcontract or 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.

21. *Do I need to submit a checklist, as I would in a federal grant submission?*
Yes. A checklist is required for each participating institution.

22. *Can you provide more information about the subcontracting process?*
All institutions included in each pilot or developmental 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 is true 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) you will still need to execute a separate subcontract for your pilot or developmental project, if awarded. We are treating each project as completely separate subawards.

If your institution is participating in more than one pilot project and awarded for more than one, each project will be treated as unique projects and will therefore have separate subcontracts.

23. *Can my institution include a lower indirect rate than my institution's Federally-approved indirect rate?*
Yes, if your institution agrees, you can indeed include an indirect rate that is less than your Federally-approved indirect rate. If you do go that route, as part of your budget justification, please include documentation of your institution's usual Federal rate and the base upon which it is calculated (for most institutions, that is the Modified Total Direct Costs, although for some it might be Personnel Costs only). 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 (e.g., Kaiser Permanente Northern California) may not be willing to do so for their portion of your overall budget.

24. *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 pilot studies 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 project the enrollment of women, minorities, and children.

25. *Do I need IRB approval for my Pilot Project?*

You do not need IRB approval prior to submitting either a Letter of Intent or a Full Developmental or Pilot Project application. However, in general, research projects that involve human subjects, including pilot projects funded under this Program, will require IRB approval. This includes data-only projects with no participant contact that use data, such as from electronic medical records, collected from human subjects. 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 Pilot Project, given a projected August 1 start date but recognizing that final funding decisions are unlikely to be made prior to the end of June.

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

26. *Do I need formal institutional signatures to submit a Full Developmental or Pilot Project application?*

From the CRN's perspective, we do not require formal institutional signatures at the time of submission of a Full Developmental or Pilot Project proposal. However, your institution may require that budget preparation and estimates, in order to be as accurate as possible, may 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.

Formal institutional signatures will be required if you are successful in receipt of a Developmental or Pilot Project.

27. *What is the source of funds for these 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. As described above, 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 Developmental or Pilot Projects.

28. *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.

I am interested in applying for pilot funds in collaboration with several others. None of the other investigators will be paid through our grant but should we still submit biosketches for them?
Yes.

Do projects have to be multisite?
No.

Can data be collected at non-CRN Sites?
Yes.

Q: If funds are not used in the one-year funding period, will PIs be able to request carryforward?
A: No

Should the abstract follow NIH guidelines? 31 lines of text?
Yes, please try to. We will still review applications with longer abstracts.

Include more information about the multi-institution budget

I am working on the proposal for the pilot project and had a logistics question. We are working on a multiple PI project with Dr. Stephen Van Den Eeden and wanted to know when we submit should we merge the two budgets together into one pdf with the two budgets followed by the budget justification for the whole project? I hope this makes sense.