

Centers of Innovation (COINs)

FREQUENTLY ASKED QUESTIONS

Strategic Concerns

Q: Will you please elaborate on your answer regarding research funded via other ORD Services, such as Rehab R&D. Do you mean to say that relevant theme-based research that is funded by non-HSR&D sources should not be mentioned in the application? If you believe that these projects could be mentioned, will you please elaborate somewhat about how you and reviewers may view these projects? In what context in the application might these projects be discussed?

A: *Any project that supports the goals and the objectives of the strategic plan should be included in the application. This can include projects funded by program offices, QUERI or other ORD services such as RR&D. However, projects that are funded by entities other than HSR&D will not count toward infrastructure support nor will they be considered projects that count toward COIN eligibility.*

Center Collaborations on a COIN

Q: Can two Centers “merge” to submit a COIN proposal?

A: *Two Medical Centers may consider submitting a **Multi-Institutional** COIN application providing the following 3 criteria are met:*

- 1) *Submission as a Multi-Institutional COIN application must be discussed with HSR&D leadership prior to application submission.*
- 2) *Investigators at each medical center will have major responsibility for the management and research activities of the COIN, either by contributing unique and complementary expertise or by demonstrating fully integrated responsibilities for developing and implementing the COIN’s strategic plan.*
- 3) **Each Medical Center must meet the eligibility criteria to apply as a COIN.** *Specifically, the minimum eligibility criteria for COIN submission are five unique HSR&D Principal Investigators (PIs) at each Medical Center who are funded or approved for funding by November 1, 2012. (see description below of eligible projects).*
- 4) *In situations where only one of two closely affiliated HSR&D funded investigator groups meets eligibility for a COIN application, the close affiliation may be discussed as part of the strategic plan of the Medical Center that is eligible to submit a COIN application. For example, the COIN application of the eligible Medical Center may discuss the following:*

- *The history of collaboration between the groups of investigators may be discussed as providing capacity that is not provided by either Medical Center alone.*
- *Collaborations between the groups of investigators on one or more focused areas of research may be discussed in the strategic plan of the Medical Center applying for the COIN.*
- *Shared mentoring and training activities across the closely affiliated groups may be cited in the strategic plan, especially where the shared career development effort of the two Medical Centers adds value beyond what is provided by either one of the Medical Centers alone.*
- *Joint collaborations with clinical and operational partners across the two Medical Centers may be discussed as activities that may contribute to or provide infrastructure for HSR&D funded projects or for QUERI projects.*
- *Mutual sponsorship of a QUERI program may be discussed as providing a shared pathway to implementation of HSR products to the clinical and operational settings.*

In applications where only one of the Medical Centers meets COIN eligibility, it will be important to show in the application that the affiliation can be sustained and that the affiliation will strengthen and not weaken the HSR&D funded efforts at both Medical Centers. For example, the application may include a discussion of how the affiliation will lead to an increased number of eligible PIs from both Medical Centers and will result in a Multi-Institutional COIN application submitted in response to the next COIN RFA. In addition, as in a Multi-Institutional COIN application, the eligible Medical Center should demonstrate efforts to collaborate with other groups of HSR&D funded investigators beyond their collaborations with the closely affiliated site.

In both cases -- a) Multi-Institutional COIN applications and b) Medical Centers submitting a COIN application that will include a clear affiliation with a group of HSR&D funded investigators at another Medical Center – the Principal Investigators should discuss their applications with the HSR&D Director and Deputy Director.

A multi-institutional COIN will receive 130% of the fixed infrastructure support provided to a single institution COIN and all of the projects at each site will count towards calculation of the variable infrastructure support.

Q: What is the difference between a “Merger” and “Collaboration”?

A: *The COIN RFA does not refer to mergers. Please see the guidance on Multi-Institutional COIN. The COIN RFA does refer to the encouragement of several types of collaboration. Examples include:*

- *An investigator team at one Medical Center can be responsible for a project that advances the goals of a COIN located at another Medical Center.*
- *Individual investigators and research personnel at a Medical Center may collaborate on projects based primarily at another Medical Center that has a COIN.*
- *Two COINs may jointly lead a QUERI Center or an HSR&D funded initiative.*
- *Mentors at one COIN may provide career development support at another COIN or at Medical Centers that do not have COINs.*
- *A COIN may provide infrastructure support for collaborating investigators who are located at a Medical Center that does not have a COIN.*
- *Several COINs may cooperate in providing a service, such as hosting a field-based meeting, special issue of a journal, or a State of the Art (SOTA) meeting. .*

Q: Can you have a multisite COIN with an additional affiliated site? So, two main facilities that meet the criteria and then an additional affiliated site?

A: *It is possible, but unlikely, that this configuration (a Multi-Institutional COIN with a close affiliation with a group of HSR&D investigators located at a third Medical Center) would be compelling in a COIN application. The success of this application would depend on the need for the third site in the strategic plan and presentation of a strong structure for the management of the three groups of HSR&D investigators. The management structure for a Multi-Institutional COIN is expected to be complex, and there would need to be very strong justification to include a third affiliated group. The application would need to present a strong case that the third affiliated site contributes to, and does not detract, from, the overall effort. Teams that are considering such a structure should inform the HSR&D Director and Deputy Director prior to submitting the RFA.*

Investigators, Projects and COIN Eligibility

Q: In a Multi-Institutional COIN, can PI's from both institutions (COEs and/or REAPs) count towards the 5 PIs needed to meet the eligibility requirement for COIN submission?

A: **Each** *Medical Center must meet the eligibility criteria to apply as a Multi-Institutional COIN. Specifically, the minimum eligibility criterion for submission is five unique PIs located at each of the participating Medical Centers on the date of submission of the application (November 1, 2012). An eligible PI is one who has a 5/8ths appointment and is the PI on an HSR&D funded project or a project that has been approved for funding by November 1, 2012. (see criteria below)*

Q: What projects can be counted towards the criterion that each COIN have a minimum of 5 unique PIs?

A: The following multi-year, competitively funded peer-reviewed awards count toward COIN eligibility: IIR, NRI, SDR, Special Solicitation, QUERI SDP, and CREATE projects. One PI who has a Career Development Award (CDA), but who does not have one of the other awards listed above can be counted as one of the unique HSR&D PIs. Each eligible PI must have a 5/8ths appointment. Projects must be active on November 1, 2012 (including project modifications) or have been approved for funding at the Summer 2012 review meeting. Projects that DO NOT count towards eligibility include: Core support for HSRD and QUERI Centers; Research Career Scientist awards; QUERI RRP; SHP (short term projects); evaluation centers or demonstration labs funded by program offices (e.g., PACT Demonstration Labs, Specialty Care Evaluation Centers, OAA-funded Centers of Excellence in Primary Care Education); research projects funded by other ORD services; projects that have concluded before November 1, 2012.

Q: How will the second round CREATEs be handled as far as eligibility and core? I ask since it is unlikely that they will be active by November 1.

A: For CREATE, IIR, QUERI, and other projects that are considered in COIN eligibility, those projects that are approved for funding by November 1, 2012 can be used in the counts of unique PIs. The project does not need to have completed Just-in-time requirements and does not need to have completed SDP conditions to have been approved for funding.

HSR&D leadership will carefully evaluate any CREATE projects, critical to a COIN achieving eligibility, and determine whether the CREATE or the specific project is likely to be funded. Notification that the COIN has met the eligibility criteria will be communicated to the COIN as soon as possible following the August SMRB.

Q: What is the effect of multi-PI projects on eligibility (including any project applications for review in August)?

A: If HSR&D leadership has approved the project as a multi-PI project, then each PI can be counted toward COIN's eligibility at their respective Medical Centers.

Q: For purposes of eligibility, are QUERI Center, VIREC Center and RRP considered "special solicitations"? Does being a QUERI Center Director or having other leadership roles such as HSR&D Center of Excellence Director, Resource Center Director or Training Program Director count as being a PI with HSR&D funding for purposes of the minimum of 5 investigators?

A: *No, QUERIs, Resource Centers, and RRP*s do not count as special solicitations toward eligibility for a COIN application. The awards that do count toward eligibility are multi-year research awards. While infrastructure support and leadership positions associated with QUERI Centers, HSRD Research Centers, or Resource Centers (VIREC, HERC, and CIDER) do not contribute to the number of individuals who can be counted toward the minimum of 5 unique investigators required of a COIN, these leadership positions and Centers should be discussed in the application as demonstrating capacity, leadership and management success, and service experience. In addition, co-located QUERIs and Resource Centers can be discussed as contributing to the strategic goals and objectives of a COIN.

Q: Why are Career Research Scientists not included in the count of funded investigators for COIN eligibility? They have counted in the past.

A: *An eligible PI is one who has a 5/8ths appointment and is the PI on an HSR&D or QUERI funded project. If a Research Career Scientist meets these criteria, s/he will be counted as a unique PI toward the eligibility of the COIN. Research Career Scientists will count towards the research activity equivalents (RAEs) used to calculate the*

Q: Do QUERI RRPs, funded through HSR&D, count as one of the criteria for eligibility to apply for a COIN?

A: *No. Service-Directed Projects (SDPs) do, but RRP*s do not. The awards that are considered toward eligibility are those that are multi-year research projects.

Q: Do CSP projects count towards PI eligibility?

A: *No, PIs who have projects funded by other ORD services (e.g., CSP) do not count toward COIN eligibility. The only exception to this rule is that a PI of an RR&D funded project can be counted toward COIN eligibility at a Medical Center where the research program has been jointly funded by HSR&D and RR&D.*

Strategic Plans, Core Investigators, and Infrastructure Support

Q: There is no mention of University affiliation, should this relationship NOT be mentioned in the application?

A: *Any collaboration or affiliation that supports the goals and the objectives of the strategic plan should be included in the application. University affiliation is important to discuss as part of the infrastructure that will be available to support a COIN. For, example, it will be important to discuss the role of the University affiliate in the advancement of Core Investigators as faculty members and in the joint recruitments of Health Services Research faculty members who will contribute to the growth of the COIN. The ability of the University affiliate to attract research funds, e.g., NIH, NSF,*

DoD, foundation, that will sustain the COIN should be considered in the application. The role of the COIN leadership and Core Investigators in leadership roles in the University affiliate will be critical to discuss as a part of the strategic plan. Other contributions of the University affiliate that should be mentioned in the application include its ability to foster an intellectual environment by sponsoring seminars and training experiences, to provide a home for mentors and collaborators, to provide resources such as space and shared equipment, to participate in contracts and IPAs, and to provide research administrative support (e.g., IRB, library and information resources, administration of non-VA research funds).

Q: In the past, the 2-year clock for obtaining funding as a new investigator started ticking if the person’s HSR&D career began as a trainee. Is this still the case? The definition includes “been employed for less than two years.” Does this mean funded (employed) solely by HSR&D? For example, when would the 2-year clock start for a CSR&D CDA who has become involved in health services research?

A: The 2-year interval is relevant only for defining “Core Investigators” for the purposes of the COIN application. New investigators who have not yet received HSR&D funding do not count towards the eligibility to submit a COIN application, but they are an important source of research capacity and can be counted among a COIN’s Core Investigators. The two-year clock is expected to begin as soon as the new investigator becomes a PI at the Medical Center and joins the COIN as a Core Investigator. The application should articulate clearly how each Core Investigator fits in the strategic plan of the COIN and will contribute to the strategic goals and objectives of the COIN.

Q: Are 5/8ths VA investigators whose primary role is as a CDA mentor considered core investigators?

A: A 5/8ths VA investigator whose primary role is as a CDA mentor may be considered Core Investigators if they have or have had in the last two years an active HSR&D or QUERI project or if they collaborate on one or more projects of the CDA recipient or other Core Investigators in the COIN. An investigator serves solely as a mentor and who does not contribute as the PI or as a Co-Investigator on VA HSR&D or QUERI funded projects would not be considered as a Core Investigator.

Q: How are CREATE projects conducted at different sites counted toward the COIN infrastructure formula?

A: Each CREATE project counts toward the infrastructure at the site where the project PI is located. Thus, a COIN that has a CREATE program will get infrastructure credit only for those projects where the individual project PI is at the COIN. In the case of a Multi-Institutional COIN, CREATE projects led by a PI at either site will be counted toward the Research Activity Equivalent (RAEs) used for calculating COIN infrastructure funding.

Q: How does a role such as being responsible for cost analysis on a CSP project get credited toward Core status? Can investigators who have participated on projects funded by operations but using HSRD methods (for example, the PACT demonstration labs) be counted as Core Investigators?

A: Core Investigators are those investigators who are integral to carrying out the strategic goals and objectives of the COIN. Investigators whose only involvement has been in support of projects funded by other ORD services (e.g. CSP, RR&D) or only projects funded by partners should not be counted as Core Investigators unless these projects are planned activities that are part of the strategic plan.

Q: In assessing research with partners -- not for infrastructure costs, but as alternatives to CREATES -- will evaluations funded by medical care dollars count?

A: Research with partners funded by medical care dollars can be considered as contributing to focused areas of research. If an evaluation or implementation is planned as one of the focused areas of research, as in a CREATE, the other projects should be foundational health services research that moves forward the science in the area of focus.

Q: How do we classify 5/8th or greater investigators who are PIs of other federally-funded projects?

A: An investigator who is 5/8th or greater and who has funding from other federal agencies can be considered as a Core Investigator if that investigator contributes substantially to the strategic goals and objectives of the COIN and who collaborates on HSR&D funded projects. An investigator who is funded through other non-VA HSR&D sources and whose work does not contribute to the COIN strategic goals and objectives would not be considered a CORE Investigator even if they are 5/8ths VA or greater.

Q: There are specific FTEE requirements and eligibility guidelines listed for COIN Directors. There is significantly less guidance around Associate Directors. Are there FTEE commitment requirements and eligibility guidelines for Associate Directors and, if so, what are they?

A: Please see page 16 of RFA.

“COINs must also have at least one Associate Director. The Associate Director must: Have at least a 5/8ths VA appointment; Report to the COIN Director; Devote at least 50 percent effort (0.5 FTE) COIN activities; and At least one of the Associate Directors must be a physician with a clinical appointment, unless the COIN Director is a physician with a clinical appointment.”

When a COIN elects to have multiple Associate Directors, the total amount of effort must meet or exceed 50% with at least one associate director at the 40% level. The amount and balance of effort across multiple Associate Directors should be strongly justified in the COIN application in any discussion of COIN leadership and management as well as in the budget justification section.

Q: Do we need to have HSR&D approval of Executive Steering Committee members before the application is submitted?

A: *No.*

Q: Do sites that have a CREATE need to propose another CREATE as part of the COIN application?

A: *No. However, medical Centers that have a CREATE may consider including other focused areas of research in the strategic plan of their COIN application.*

Review Criteria and Concerns

Q: Please provide more detail regarding the review criteria. Will there be documentation of these criteria?

A: *There are five criteria, all of which are documented in the RFA:*

- *Strategic plan (including CREATE elements)*
- *Emerging research activities which do not contribute directly to the strategic plan*
- *Mentoring/career development*
- *A combination of efforts to promote collaboration and partner service*
- *Overall institutional strength and research capacity (including prior productivity, institutional support, and academic affiliates)*

We recognize the importance of diversity among the HSR&D COINs. To enhance opportunities for diversity, we have not assigned fixed weights to these criteria. As part of the review, a score will be requested for each criterion. The strategic plan and overall strength and capacity (including past productivity) will be the most important criteria, but the relative importance of each criterion may shift from COIN to COIN depending on the strategic plan for each COIN.

Funding

Q: Budget – is this something that replaces our annual budget request for our Center?

A: *No, an annual budget will still need to be submitted each year.*

Q: If the Center does not have a CREATE, should COIN money be used to support CREATE-type research?

A: *COIN infrastructure funding can be used to support initial work toward a focused area of research that is like a CREATE, partner-related and capable of producing both short-term and long-term impact. However, it is expected that any planned focused areas of research will be supported by HSR&D, QUERI, or partner funds as soon as possible after the approval of the COIN.*

Q: How will medical care funded research initiatives be handled in the funding equation (e.g., PACT Demo Lab, SCAN Evaluation Centers, etc.)?

A: *Only HSR&D funded projects are being “counted” as part of the infrastructure formula. We are aware of the fact that medical care funded research initiative require infrastructure support and we plan to develop strategies to address those requirements.*

Q: What project funding years should be used when calculating the three-year average?

A: *None. The three-year average is a figure that will be calculated by HSR&D Central Office to determine infrastructure support for COINs. For funding that will begin in FY 14, the three-year “look-back” will be based on research activities in FY13, FY12, and FY 11. Funding for FY15 will be based on research activities from FY14, FY13, and FY12.*

Q: If the three-year average is not something applicants supply, which three years of productivity should be included in the application: FY10 through FY12, or FY09 through FY11?

A: *Research activities funded in FY 10, FY 11 and FY 12 should be included in describing research productivity. Projects reviewed during the Summer 2012 cycle of the Scientific Merit Review Board and approved for funding by the November 1, 2012, deadline may be included even though the project has not completed its JITs or SDP conditions.*

You have broader latitude to discuss completed projects that are relevant to your expertise in research focus areas and which may have shaped your strategic plan.

Formatting and Submission Guidelines

Q. A table/appendix is not described in the RFA for the Mentoring and Career Development section, although we are asked to provide a list of current and prior CD recipients. Should we include a table as a separate appendix?

A. *Yes, please include the list of current and prior CD recipients as a separate appendix. Please follow the standard naming convention used for the other listed tables.*

Suggested name: “21_VA_Appendix_12_CDARecipients.pdf”

Q: 16_VA_Appendix_7_Coin Investigators.pdf (page 38) and 19_VA_Appendix_10_COIN investigators and staff.pdf (page 43): Do we end up having two tables with investigators in them?

A: *Yes, there are two separate tables that list investigators.*

Q: Can we include non-HSR&D funding on our COIN Investigator table?

The COIN Investigator Table included in Appendix 7 is a table of Core Investigators. These are individuals who are 5/8th VA and who are Principal Investigators or Collaborators (e.g., biostatisticians) on HSR&D-funded projects including QUERI. Investigators who have no HSR&D funding should not be listed in the CORE Investigator Table.

A table of COIN Investigators and Staff in Appendix 10 includes all COIN Investigators and Staff members, including non-Core investigators. If an investigator who has no other HSR&D funding contributes to the strategic goals of the COIN, this investigator might be listed here as a non-Core investigator. However, the decision to include this investigator in Appendix 10 should be based on their contribution to planned activities that are part of the strategic plan. It should be noted that projects that are funded by entities other than HSR&D will not count toward infrastructure support nor will they be considered projects that count toward COIN eligibility.

Q: Page 10 of the RFA says that there's a 25-page limit, PLUS 1-2 pages for Executive Summary. But on page 26, it says we are NOT using the Specific Aims document (have to put in a placeholder for it, as the SF424 requires something there). It goes on to say that the Research Plan, which includes Strategic Plan, Mentoring/Career Development, Cross-Medical Ctr Collaboration, Service Activities, Implementation Capacity, Prior Productivity & Impact, Ctr Leadership, Ctr Org/Management, COIN Investigators and Staff, and Available Infrastructure/Institutional Support, can only be a total of 24 pages. So is it 25 pages Plus 1-2 pages, OR only 24 pages? This is a big difference when there's so much that has to be covered.

A: *The Research Plan is limited to 24 pages. The Executive Summary is a separate document and is limited to 1-2 pages and is uploaded as "10_VA_Appendix_1_Executive Summary.pdf".*

Q: The section on Human Subjects doesn't seem relevant. Do we need to include this?

A: *It is relevant, as most all HSR&D projects will include human research participants. Per the RFA (page 32), it states that "This attachment is required if you checked the box marked "Yes" for Question 1 on the Other Project Information Component (Are Human*

Subjects Involved?) Since HSR&D proposals usually require IRB approval or exemption, —Yes it should be checked and this attachment included.”

Q: How should we approach this as a multi-institutional COIN? Most of our future proposals will have, at minimum, COIN investigators from each COIN site on the proposal. Will we qualify to use the Central IRB since we will be one COIN but with two sites?

A: The question asks about how to write the human subjects section of the application. We would suggest that this section include a description of how human subjects will be handled in the Multi-Institutional COIN. The following information would be relevant.

- *Specify the IRB of record for each medical center participating in the Multi-Institutional COIN;*
- *Discuss how IRB submissions will be handled for investigators from each of the institutions involved in the COIN;*
- *Describe how IRB submissions will be handled for collaborations across the two institutions involved in the COIN as well as how IRB protocols will be handled for collaborations with other investigators external to the Multi-Institutional COIN;*
- *Indicate when the Central IRB would be involved in a protocol submitted from either of the medical centers participating in the COIN.*

Q: Do we enter all Core PIs in the Sr/Key Personnel section of the SF424, and then attach a biosketch and other support for each one? The RFA doesn't address this.

A: Yes, enter all Core PIs in the Senior/Key Person Personnel Section and include their Biosketches and Current & Pending Support.

Q: Will biosketches, other support information, and letters of support be required for both Core Investigators and non-Core Investigators in the COIN application?

A: See Table 1 on page 25 of RFA. Biosketches and Current & Pending Support are required for Core Investigators. Letters of support are not required for Core or non-Core Investigators unless they are located at a site different from that of the main COIN site.

Q: Other requirements for attachments in the SF424 are not mentioned in the RFA: Narrative (up to 10 lines, essentially the relevance part of what we'd consider an abstract) and Abstract (40 lines, the rest of what we'd consider an abstract), Facilities & Resources statement, References. Are we supposed to provide pdfs for all of these? Or are we supposed to leave the boxes for these on the SF424 blank? Especially since Resources is 15_VA_Appendix_6_COIN infrastructure and institutional support.pdf.

A: Please see Table 1 on page 25 of RFA. They should be provided as instructed in the SF424.

Q: There are some differences between the RFA narrative describing the components of the different sections and what's described in Table 2 of the RFA. Which instructions should we focus on?

A: Please focus on the instructions for Table 2, because these provide more detail.

Q: Can you provide examples of the tables for 13_VA_Appendix_4_Coin leadership organization, management plan, infrastructure and institutional support and 15_VA_Appendix_6_COIN infrastructure and institutional support?

A: These two appendices do not need to be in a table format.

Q: Is a separate MOU from the VAMC Director needed in addition to a letter of support from the VAMC Director? It seems that these would include essentially the same things.

A: You may include this information in the Director's letter (08_VA_Director_Letter.pdf). If you do, please still upload pdf document "14_VA_Appendix_5_Memorandum of Understanding VA Director.pdf" with a statement indicating that memorandum of understanding is included in the VA Director's Letter.

Q: The RFAs for HSR&D and Rehab R&D Merits state that the support letters should be named 08a_VA_Letter and the checklist refers to the support letter attachment as 08b. For inclusion in these merits should the attachments be named with 08a or 08b?

*A: The attachment filename for the Letters of Support PDF should be **08a**. There is a new attachment 8a. The checklist reflects that a R&D Committee Letter is required for RCS application; however, the R&D Committee Letter is no longer required of other application submissions.*

Q: Can you give more details on what the CREATE appendix should look like for those centers WITHOUT a submitted or funded CREATE?

A: The page limit is the same as for the CREATE overview, 10 pages. The overview should include a description of the same elements as the CREATE overview, but should include more detail about the individual projects. (This is to compensate for the fact that the CREATE overview does not include project details, which are provided as part of the individual project descriptions.)

Each center must provide a 10-page appendix describing their integrated, collaborative, partner-engaged research projects including how they relate to each other; how partners have been part of the process of developing them; and how those projects will, together, contribute to having impact. For those centers that do not have a CREATE (or a CREATE under review), this description should describe planned or funded projects

and clearly demonstrate how the partner has been involved. For more information please see page 27 of the CREATE RFA.

Q: Regarding cross medical center collaborations, the instructions ask us to list collaborations our investigators have with other centers, but not how investigators from other centers are include in our work. Would the reviewers want to see both types of collaborations highlighted?

A: *The RFA requests that both types be documented. Please see page 28 of RFA.*

“It will be important to show how the Center plans to develop new collaborations across medical centers and how the Center plans to sustain existing and new collaborations extending into the future. For example, describe how investigators at other sites will be involved in work on strategic initiatives for the COIN or will lead specific projects within the COIN’s focused areas, including CREATEs. It will be important to indicate how the COIN plans to support investigators who participate in research and mentoring activities at another COIN.”

Q: It is my understanding that IPAs for personnel at academic affiliates have a maximum 4-year time limit and then there must be a break in service. – Will this change with the COIN?

A: *No, it will not change. The Office of Personnel Management (OPM) governs IPAs and the four-year time limit is based on OPM policy.*

Human Subjects

Q: How should we answer questions like the inclusion and exclusion criteria, sources of material, recruitment plans, etc? Which projects do we answer these questions for?

A: *This section should focus on the basic processes of ensuring human research participants protections at the applicant facility and any processes or structures that are unique to that particular facility.*

The Human Subjects section can be brief (a half page or less), but should mention that your center will involve studies of human research participants and should discuss the human research protection program and processes at your medical center. For example: Where is the IRB of record located for your facility (VA, other VA, or affiliate)? How are proposals handled by the medical center R&D committee? How are unanticipated problems reported? Where are research records stored in the center? How is privacy and confidentiality reinforced? Does the IRB of record include voting members from the COIN?

Questions Added 10-24-12

Q: Where in the application do references belong?

A: The information for the References Cited section can be found in the SF424 guidance. The SF424 application has a location where Bibliography/References Cited are to be attached. There is no page limitation

Q: To whom should letters of support be addressed?

A: Letters of Support should be addressed to the Director, HSR&D; or Dr. David Atkins, Acting Director, HSR&D.

Q: The Codes for the Appendix describing Activities in Support of Goals and Objectives are not clear. Are we expected to use these codes, or can/should we create our own? For example, P = Publication, but X definition also includes publication.

A: We selected several codes as examples. You can use your own codes in the Appendix tables and make sure it is included in the key.

Q: Are the COIN reviewers going to have access to our REAP ART report information or do we need to make sure all the information from ART that we want them to see is in the COIN proposal?

A: We are unlikely to distribute the ART report information. We would encourage you to distill the best from the previous annual report and include that in the COIN application. The emphasis would be on how you will build from your past successes to move toward more partnered research, with more emphasis on research impacts, and greater innovations coming from your research.

Q: Are we expected to resubmit partnered research IIR proposals (that we submitted in June) this coming December—how might submitting or not submitting in December (as opposed to next June) impact our COIN applications? (Several of us would find it very challenging to be able to revise these proposals adequately so soon after the COIN submission).

A: We do not have expectations that you resubmit partnered research IIR proposals in December. The strategic plan should be forward looking and you can build into the plan for developing your CREATE-like focused area of research over the next several years. However, the CREATE-like focused area of research will receive attention during the review. For that reason, we would encourage you to think about how to make a forward looking plan compelling. For example, you might show the resubmissions of your partnered research across December and June FY13, if possible to submit even one proposal in December. Alternately, you might show how you are incorporating the feedback received from the June reviews into the COIN application and next into June FY13 resubmissions.

Q: This question has to do with both the (a) Center organization and management plan, and (b) infrastructure & institutional support, which are required in the narrative and the appendix. How do we distinguish between the narrative and the appendix for each of these topics?

A: The names of the appendices are as follows:

Appendix 4. Management Plan and Support

“13_VA_Appendix_4_ManagementPlanandSupport.pdf” relates to the people leading the COIN and the governance and organizational plan proposed for the COIN.

Appendix 6. Infrastructure and Institutional Support

“15_VA_Appendix_6_InfrastructandInstitutSupport.pdf” relates to the environment and infrastructure to support to conduct research. This would include such as leveraged resources from the Medical Center, VISN, academic affiliate, and VHA partners. Infrastructure support might include space, furniture, conference rooms, telecommunication capacity, data, statistical analytic expertise, library and information resources, seminars and educational opportunities, shared staff and expertise, etc.

Sections 6 and 9 on pages 30 and 31, respectively, discuss the Research Plan narrative. In this section, the appendices that support specific parts of the research plan narrative are noted. The full description of the appendices is provided later in the section on appendices (page 37).

Because of the limited space allowed for the research plan narrative, we suggest that you use the appendices to include additional detail on the management plan, infrastructure, and support. We anticipated that most groups would want to include more information on their strategic plan in the narrative and would want to devote less space to the basics such as management plan and infrastructure. As a general principle, we had expected that the appendices be used like tables and figures in a scientific paper. They should provide data that support the text in the narrative. However, some of the appendices request text that we thought was less important to include in the narrative, but still useful to reviewers in evaluating your application and would allow you extra room to elaborate on your strengths. If you believe that both a narrative and table in an appendix will support the narrative in the research plan, please do use both narrative and table.

Q: For the other appendices, do you just want tables, or can we also include some narrative? The instructions for the appendices (pp. 35-37) describe both narrative and tabular components; but the instructions on p. 34 regarding the appendices state, “Do not use the Appendix to circumvent the page limitations of the Research Plan.” So, it’s not really clear whether we can put any narrative in the appendices, and, if so, how much?

A: As a general principle, we had expected that the appendices be used like tables and figures in a scientific paper. They should provide data that support the text in the narrative. However,

some of the appendices request text that we thought was less important to include in the narrative, but still useful to reviewers in evaluating your application and would allow you extra room to elaborate on your strengths. If you believe that both a narrative and table in an appendix will support the narrative in the research plan, please do use both narrative and table.

Q: Several of the directions for the appendices (e.g., p. 36 under Service Activities) state, "In the narrative...". Does this refer to the narrative in the appendix, or the larger narrative? Since this is stated in the appendix instructions, we're assuming this refers to a narrative component of the appendix. But then it gets a little murky because the content seems to overlap with the bigger narrative.

*A: The RFA includes Table 2: Other Project Information Component Attachments for Item 12. These attachments include the research plan and the appendices. Table 2 starts in page 26 and goes to page 43. The research plan is discussed starting on page 26 and refers to a narrative. The appendices are discussed starting on page 34. On page 36, an appendix on service activities is discussed--**"12_VA_Appendix_3_ServicetoHSRDandHealthSystem.pdf"** This section begins with a request for a narrative description: "In a narrative, describe separately activities that provide service to HSRD..." This section also includes a request for a table "Include a table of service to HSR&D that lists..."*

While there is overlap with the research plan narrative, the purpose in allowing you to have narrative here in the appendix is to provide space for you to expand upon services briefly summarized in the research plan. I would not repeat narrative in both places, but expand in the appendix. We thought that the description of services in the research plan may be so brief that additional details may be useful here.

Q: On the COIN Budget in grants.gov, do we also include donated clinical staff as we have done so in the past for our COE Budgets?

A: Yes; please refer to SF424 under "Senior/Key Person".

Q: According to page I-62 on the SF424, it is unclear if the system allows a maximum number of personnel.

A: More than 40 can be listed (not sure of total number allowed). You can add the first 40 and then an additional form attachment section becomes available – so the maximum number is well over 40. Biosketches must be included for each Sr/Key person as an attachment.

Q: Should we include travel in our budget or are we getting separate travel funds?

A: All travel must now be submitted to CO for approval-we are not sending out discretionary travel funds. The COIN budget should NOT include any request for travel funds.

Q: We are partnering with PIs at other sites on projects related to one of our Focus Areas (it is not one of their focus areas). Thus, I wanted to list them under projects in Appendix 9 that align with our Goals and Objectives. Is this allowed? How will this be viewed? I also am not sure how to highlight our roles in the grants since we will play a significant role with them.

A: You may use the project as part of your strategic plan to show collaboration and that is an important component. It is ok to include the project under the “Activities in Support of Goals and Objectives Table”; we would suggest amending the table key to indicate that the project is not from your center. You may not count the PI as one of your core investigators. You should also get a support letter to document the collaboration since that project is not at your site.