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**Department of Veterans Affairs  
Veterans Health Administration  
Office of Research and Development**

**Instructions for Submitting a Letter of Intent  
to Apply to Pilot the Network of Dedicated Enrollment Sites (NODES) Initiative**

**1. Purpose.** The Veterans Health Administration (VHA) Office of Research and Development (ORD) invites Letters of Intent (LOIs) to apply to pilot a Cooperative Studies Program (CSP) initiative involving a **Network of Dedicated Enrollment Sites (NODES)**. This initiative aims to establish a consortium of VA medical centers (nodes) that are dedicated to the multi-site clinical research mission of CSP. Individual nodes will be a component of the national CSP organization responsible for conducting clinical trials. *The NODES initiative is meant to supplement, not replace, the existing model of individual medical centers participating in collaborative studies.*

The initiative seeks to provide efficiencies and economies of scale for CSP studies. Specific aims include: enhancing study performance and enrollment rates; providing a more consistent and comprehensive approach to CSP study management, quality and regulatory compliance at VA medical centers (VAMCs); obtaining center-level perspectives in the design and execution of studies; and providing opportunities for research personnel interested in supporting the CSP research mission.

**2. Background.** CSP has a long and successful history of completing definitive multi-site clinical trials. Individual trials are designed and implemented by one of five CSP Coordinating Centers (CSPCCs) supported by a Clinical Research Pharmacy Coordinating Center (CRPCC). Recruitment sites for studies are selected from among VAMCs with an appropriate patient population, eligible clinical investigators and a research environment conducive to achieving study goals.

Typically, participating sites are selected and study personnel hired following approval for study funding. CSP studies at a given medical center operate independently of one another. While this model has served CSP well in the past, delays in study start-up, inconsistent site performance and the inability to conduct systematic evaluation and strategic planning have resulted in a need for novel approaches to conducting multi-site studies. Research personnel may or may not have prior clinical research experience and are only retained for the duration of the specific study. Further, the time and resources for study startup often exceeds that available to principal investigators and study staff. There are also growing challenges with meeting administrative, training and/or regulatory requirements that can contribute to delays in completing studies. More efficient study processes are needed to avoid increased study costs and to improve the overall ability to inform stakeholders of study results in a timely manner.

Accordingly, CSP is piloting the NODES initiative through which funded sites will establish CSP research groups that will be prepared for and capable of a more nimble response to new studies. Applicants selected to participate will receive support for

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personnel to organize and coordinate multiple CSP studies at a VAMC. At a minimum, a node is expected to have a Director and Manager (see descriptions below) and may request additional administrative staff if the need is sufficiently justified to meet the initiative objectives. Individual nodes will be integrated into the national CSP organization and receive the support, experience and opportunities offered by the program. A more detailed description of the initiative can be found in Attachment A.

**3. Overview of the NODES Initiative Structure and Responsibilities.** Each node will have administrative and research related responsibilities. These responsibilities will include the coordination of study personnel and activities for ongoing CSP clinical trials at its respective VAMC, assisting with study initiation activities for new studies and developing an organizational structure and procedures for long-term sustainability of the network. CSP clinical trials will be accomplished through a hybrid model consisting of nodes and independent (non-node) VAMCs. Further, nodes will collaborate with CSP Centers and Central Office in national-level discussions related to organizational, administrative and scientific strategic planning activities for the program.

**4. Overview of an Individual Node Structure and Responsibility.** The core structure of a node will consist of a node Director, node Manager and an administrative/research assistant (if needed). Research personnel associated with active CSP trials at the facility will be expected to become part of the node. The node core will be expected to develop a plan for coordinating local CSP activities and helping to transition such efforts into a team-based approach for conducting all CSP clinical trials at the VAMC. New node research coordinators will be recruited, if needed, and funded by separate CSP study budgets. Ultimately, a node is expected to be a coordinated team of research personnel that can cover study coordinator responsibilities, work with local Site Investigators to enable their success and contribute to the overall clinical research environment locally and nationally.

The *node Director* should have experience in overseeing clinical trials within VA. The individual must have strong knowledge of the local VA medical and research communities and have experience with identifying and obtaining necessary resources and support for research efforts. He/she will be accountable to CSP and to local VAMC leadership through the Associate Chief of Staff for Research and Development (ACOS/R&D).

*General Responsibilities of the node Director* will be to:

- a. Interface with local leadership within VA and the research community to develop a high performing node, advocate CSP activities and promote a “culture of clinical research” at the facility;
- b. Liaise with CSP to oversee local node operations to assure an ongoing quality program; provide executive and administrative support for the node; and work with the node Manager to secure resources such as space, staff and administrative/IT support for the node; and

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- c. Oversee job performance of the node Manager; report regularly to CSP leadership and ACOS/R&D (or other local designee) on node status, issues and progress; and intervene as needed for issue resolution.

The *node Manager* should be an experienced research coordinator familiar with managing all phases of a clinical trial. Clinical research certification (e.g., CCRC, CCRP, CITI, CRA) is desirable. He/she must have strong management and communication skills and an ability to collaboratively work within the local VA medical and research communities. While nurse research coordinators will likely fulfill the requirements, having a nursing background/experience is not a requisite element for this position.

*General Responsibilities of the node Manager* will be to:

- a. Oversee and manage all aspects of ongoing and new CSP studies within the node. This individual will work with CSP to help evaluate study feasibility, facilitate regulatory processes, assist in compliance with regulatory requirements, maximize recruitment efforts, assure patient safety and maximize quality and timely data collection;
- b. Integrate current CSP study coordinators and, if needed, recruit new study coordinators and support staff for the core node group; manage funding allotment and assignments for CSP studies; oversee and manage performance, training and salary allocation of node employees; and secure resources/support as needed within the local VA for specific CSP studies; and
- c. Contribute to national efforts for developing lessons, procedures and standards to enhance future NODES operations and individual VAMC activities for CSP studies.

All studies at the VAMC will still require a local *Site Investigator (SI)*, usually a practitioner in the subject area of the study. The SI will retain ultimate accountability for the conduct of the study and will work closely with the node staff to ensure study success. The SI will attend all study functions including kick-off, annual and final meetings, and will participate in study-site conference calls. The responsibilities of the SI include overall conduct of the study in accordance with Good Clinical Practices and other requirements as specified by individual protocols. Node personnel are expected to have good working relationships with SIs and to work collaboratively to achieve study goals and comply with regulatory requirements.

**5. Eligibility.** Applications may be submitted by any VA facility with a Federal Wide Assurance (FWA) to perform human subjects' research and with interest in supporting the CSP mission to conduct definitive clinical research studies that support evidence-based medicine. Only one application may be submitted per medical center. Additional requirements for applicants include:

- a. At least two clinical trials at their VAMC with CSP-funded study coordinators at the time of the LOI submission - This requirement is to enable the node to meet a primary pilot objective of coordinating multiple CSP activities at a VAMC.

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b. The ability to initiate a diverse set of CSP clinical trials and to recruit subjects into them - A node must exist in a rich clinical and academic environment with eligible VA healthcare providers available to serve as SIs for funded projects per existing VA research policies.

c. A node Director who is at least a 5/8 FTEE VA employee - A proposed Director should have a record of collaborative clinical research and demonstrate strong citizenship in the local medical and research communities. Important qualifications of a proposed Director include: previous or ongoing CSP experience; access to local investigators and research personnel with CSP experience; demonstrated ability to manage resources; and full support from their medical center leadership as demonstrated by at least 25% protected time for node activities.

e. Ability to use the VA Central Institutional Review Board (IRB) as the IRB of record for CSP studies - CSP policy requires use of the VA Central IRB for its studies.

f. Willingness to participate in and contribute to the NODES initiative nationally - This effort will require teleconference calls and occasional face-to-face meetings to review progress, conduct strategic planning and coordinate activities for fulfilling initiative goals.

**6. Performance Criteria.** Individual node performance will be evaluated by CSP using a variety of performance metrics including:

- Time and ability to establish a node
- Time and ability to initiate a new study, including:
  - bringing on new study personnel (if applicable)
  - completing IRB submissions
  - enrolling the first patient into a study
- Recruitment rates
- Regulatory compliance and protocol adherence
- Obtaining informed consent for study participants
- Data completeness and quality
- Budget management
- Staff turnover
- Response time to queries
- Customer service
- Contribution to national CSP discussions and study planning

**7. Funding.** CSP plans to fund those applicants that demonstrate outstanding ability to achieve the goals of the pilot project and who have high levels of scientific and technical merit. For sites selected in this pilot phase, funding will be provided at a minimum for a node Manager. Funding for additional administrative staff may be provided if the need is sufficiently demonstrated to meet the objectives of the NODES initiative.

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## **8. Letter of Intent Submission Process.**

a. A Letter of Intent (LOI) must be received in CSP by April 29, 2011, for potential consideration of a full application. Full applications will not be reviewed without an approved LOI.

b. The format for the LOI is:

1. Form 10-1313-13 should be used to provide the following information:
  - i. VAMC;
  - ii. Proposed Director of the node (see additional instructions below);
  - iii. Application title; and
  - iv. Signature of the ACOS/R&D or appropriate local approving official.

2. A summary (1 page maximum) of the proposed node leadership. The proposed node Director will be the principal investigator on the application. Provide the node Director's experience and other qualifications that make him/her an appropriate candidate. If the proposed Director is not the ACOS/R&D, briefly describe the ACOS/R&D's involvement with the node. Important considerations will be prior clinical research activities and demonstrated integration into the clinical and research communities of the medical center. Additionally, this summary should include potential candidates for the node Manager and a brief description of their qualifications, or outline strategies for identifying one.

3. A description (1 page maximum) of the local scientific and clinical community, including the facility and the ability to conduct clinical trials in a broad range of health conditions.

4. A narrative (1 page maximum) stating why and how the VAMC wants to increase participation in CSP studies by participating in the NODES initiative. This may include, but is not limited to, describing how a CSP node supports local initiatives for clinical research, past experience with CSP and its processes and a plan to implement and maintain a node at the facility.

5. A listing of CSP clinical trials conducted at the medical center over the past three years, including the name of the SI and study coordinator for each study.

6. A CV for the proposed node Director.

7. A statement indicating that the facility has necessary approvals for using the VA Central IRB as its IRB of record on multi-site studies.

c. Submit the original LOI, 4 copies and an electronic version on CD to:

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Cooperative Studies Program (125)  
ATTN: NODES LOI  
810 Vermont Avenue, NW  
Washington, DC 20420

d. Inquiries may be directed to David Burnaska, CSP Program Manager, at [david.burnaska@va.gov](mailto:david.burnaska@va.gov) or 202-443-5693.

e. CSP will hold informational conference calls on this initiative. The agenda will be to review highlights of the initiative and to respond to queries from the field. Participation on a call is strongly recommended but is not a prerequisite for submitting an LOI. Details about the calls will be provided to research offices as they become available.

f. Applicants with an approved LOI will be invited to submit a full proposal for a node. Full proposals will be due roughly six weeks after notification of an approved LOI. A due date will be specified in the approval letter and proposal instructions. Full proposals should clearly delineate how the proposed node will meet the objectives of this initiative. Specific instructions for full proposals will be provided on the VA Office of Research and Development website (<http://vaww.research.va.gov/funding/solicitations>). Proposals will be submitted electronically through Grants.gov. More information will be provided in the LOI approval letter.

g. Although CSP's financial plans include support for this initiative, the number of awards pursuant to this announcement are contingent upon the availability of funds and the receipt of a sufficient number of applications of outstanding scientific and technical merit.

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## **ATTACHMENT A**

### **INITIATIVE DESCRIPTION**

NODES initiative sites have two main aims: 1) local coordination of multiple CSP clinical trials that result in their safe, efficient and high quality execution and management; and 2) contribution to the operation and organization of a national network of sites focused on improving clinical research supported by CSP.

**Conduct of Clinical Research.** Nodes will receive funding to coordinate efforts for clinical research studies supported by CSP spanning the spectrum of medical, surgical and mental health subspecialties. It will be the node Director's responsibility to serve as a local clinical and scientific leader for CSP activities related to study conduct, safety and compliance. The node Director may also be asked to help identify local experts in the discipline of interest who are willing to assume the role of SIs for the investigations. SIs will be involved in CSP studies as they currently are through activities such as study participant recruitment and conducting the study in accordance to the protocol. SIs will be the primary individual to contribute to the science and clinical impact of individual CSP studies through participation in study meetings and communications. Node Managers will be expected to provide guidance and support for study coordinators and study personnel to ensure that regulatory and protocol requirements are fulfilled. Both the Director and Manager will work with SIs to determine how to best achieve site performance goals. However, final responsibility for the conduct of a CSP study at a VAMC will continue to remain with the SI.

**Value Added to the Mission of CSP.** As part of a network, each node will be expected to provide intellectual and operational contributions to CSP beyond the context of the individual funded studies. It is expected that the establishment of a node at a VAMC will create opportunities and provide lessons for enhancing the efficiency and quality of CSP studies.

**Director.** The node Director should be an experienced clinical investigator with scientific expertise, leadership, mentoring and administrative skills to lead the node's multidisciplinary research. Node Directors should be integrated into the clinical environment of the facility and be knowledgeable of key operational and regulatory policies for VA research. The ACOS/R&D may serve as a node Director if he/she fulfills the requirements for the role.

**Collaborators.** A successful node will have collaborations with individuals who have strong interests in serving as Study Chairs or SIs in their respective disciplines. Similar to the Director, ideal collaborators should be integrated into the clinical environment of the facility, have knowledge of CSP's mission and have established records in clinical research.

**Institutional Environment.** Each node will be expected to coordinate studies and communicate with staff and stakeholders in various specialties spread throughout its

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facility. It is critical that each node exists in an environment that will contribute to its success. An important element of this environment is personnel with the strong desire and ability to reach out to the clinical and patient communities and actively engage them as partners in research. A faculty with broad clinical expertise that is integrated into both the clinical and research communities of the medical center and has access to a diverse patient population is necessary. Staff on active CSP trials will be expected to participate in the node. In addition, adequate space for conducting clinical research is required. Other local strengths may include pre-existing clinical and research centers (e.g., CSPCCs, HSR&D Field Programs, MIRECCs, REAPs, ERICs, GRECCs) and educational programs (e.g., NIH K-type awards), as well as a strong relationship with a local VA nonprofit research and education foundation, if applicable.

**Allowable Costs.** *Funding of the pilot NODES initiative is expected to be for 30 months and consists of the following:*

- a. Administration. Funding will be provided at a minimum for a node Manager. Funding for additional administrative staff may be provided if the need is sufficiently demonstrated to meet the objectives of the NODES initiative.
- b. Travel. Travel funds may be requested for node staff to attend a national NODES organizational meeting, at least one CSP study annual meeting and a training meeting. Supplemental funds may be provided after the initial award once specific travel requirements are determined.
- c. Miscellaneous. Funding may be requested to cover miscellaneous costs such as office supplies, copying charges, express mailings, etc.
- d. Equipment. Funding will be provided for a dedicated secure fax machine and other items that have been traditionally covered by CSP study budgets.

For equipment that falls under the purview of the Office of Information and Technology (OI&T), applicants must be able to work with appropriate groups at their VAMC to obtain items.

All costs related to a study will be provided by the specific study budget and not through the administrative costs for the node.