

June 13, 2001

## SOLICITATION FOR APPLICATIONS TO ESTABLISH HEPATITIS C FIELD-BASED RESOURCE CENTERS

**1. PURPOSE:** This Veterans Health Administration (VHA) Notice announces the opportunity for Department of Veterans Affairs (VA) medical facilities to compete for funding to establish one or more peer-reviewed Hepatitis C Field-based Resource Centers (HCFRC).

### 2. BACKGROUND

a. **HCFRC.** The purpose of the HCFRC program is to enhance VA's capacity to respond to the large and growing public health problems created by hepatitis C virus infection. Across the span of the 5-year funding period, HCFRC programs will provide clinical leadership and high quality services, products, and programs to the entire VA health care system in the areas of hepatitis C patient education, clinician education, clinical care delivery, prevention, and program evaluation.

(1) More specifically, the center(s), under the direction of the Chief Consultant for Public Health, will function as field-based clinical laboratories for the development, testing, and evaluation of a set of specific products which will:

(a) Consist of new and innovative means to improve the efficiency and effectiveness of hepatitis C clinical care;

(b) Have specific relevance to veteran populations;

(c) Be targeted for use by all VA facilities; and

(d) Improve every VA medical facility's capacity to maximize hepatitis C screening, counseling, testing and treatment efforts.

(2) Centers will play an important role in both development and implementation of VA-wide hepatitis C related projects. In the realm of program and/or product development, a number of priority focus areas have been identified and are described in paragraph 4. Each center will have at least one area of specific focus from among these content areas.

(3) In addition to these activities in program and/or product development, centers will be involved in the process of implementing and evaluating these innovations more widely throughout the VA system. Implementation activities may include the development and dissemination of education and training materials, initiation and evaluation of pilot projects or initial feasibility studies in clinical care delivery or prevention, as well as beta testing and program evaluation of new initiatives in hepatitis C.

**THIS VHA NOTICE EXPIRES JUNE 30, 2006**

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### b. Hepatitis C

(1) Hepatitis C infection is a major public health problem with growing implications. The Centers for Disease Control and Prevention (CDC) estimates that over four million Americans are infected with hepatitis C and that over 30,000 new infections occur annually. Up to 10,000 deaths per year in the United States are attributable to hepatitis C, and chronic liver disease is the tenth leading cause of death among American adults. Current CDC estimates that medical and work-loss costs of hepatitis C-related acute and chronic liver disease are over \$600 million annually. Unless there are significant improvements in therapy, the number of hepatitis C-related deaths is expected to triple in the next 10 to 20 years. Hepatitis C is currently the leading reason for liver transplantation in the United States.

(2) VHA has given highest priority to addressing the public health problem of hepatitis C. The large number of veterans infected with hepatitis C; the need for consistent, comprehensive and compassionate approaches to diagnosis and treatment; the need to ensure appropriate levels of support to all VA facilities which provide care to hepatitis C infected veterans; and the need to improve upon current treatment options all create major challenges as well as opportunities. As the largest single provider of health care to hepatitis C infected Americans, VA has both the opportunity and the responsibility for leadership in this field.

c. Rationale. The VA is uniquely positioned to become a model system for comprehensive response to the increasingly apparent public health problem of hepatitis C infection. As a nationwide care delivery system with over 1,100 sites of care organized into 22 Veterans Integrated Service Networks (VISNs) and its focus on the provision of high quality care for a defined population of patients, the VA offers a unique opportunity to plan, implement and evaluate systems and standards of care. Specific strengths of the VA system include the widespread use of uniform electronic medical record software, the ability to retain patients and to provide long-term follow up, the size of the hepatitis C infected population, the large representation in the group of racial minorities, and a strong track record of research. In addition, as a system with a strong record of advocacy for the health of veteran populations, the VA is committed to the education of all beneficiaries regarding hepatitis C infection and to the prevention of new infections, as well as the prevention of complications in those already infected.

### 3. PROGRAM POLICIES

a. This solicitation provides VA medical facilities with the opportunity to apply for 5 years of support to establish centers consistent with the purpose outlined in the preceding paragraphs. Funding is expected to facilitate the recruitment and development of a stable group of administrative, professional and technical staff sufficient to accomplish the goals of this program.

b. Funding may be requested for well-justified costs up to \$1,000,000 in the first year, and \$500,000 per year for the remaining 4 years. These funds may be used to support:

(1) Salaries;

(2) Pilot projects;

(3) Infrastructure maintenance or improvement up to a maximum cost of \$300,000 (in the first year of funding only);

(4) Supplies for core facilities; and

(5) Other miscellaneous expenses.

c. The opportunity for competitive renewal, based on the satisfactory review of a meritorious Center Continuation Application and the availability of funds, is anticipated by VHA Headquarters.

d. HCFRC management will be required to submit quarterly budget reports and a comprehensive annual report for administrative review. Continuation of funding will be reviewed annually and will be contingent upon the satisfactory accomplishment of performance-based measures, which must be identified in the strategic plan and evaluated in the annual report. Each center's annual report may be accompanied by necessary changes in its strategic and operational plans, especially to correct any performance deficits.

e. Each Center is expected to work collaboratively with other funded centers and VHA programs and offices, as appropriate, and as directed by the Office of Public Health and Environmental Hazards. This will involve regular meetings and conference calls, as well as collaboration on joint projects.

#### 4. PROGRAM REQUIREMENTS

a. **Applicant Sites.** Applicant sites may be a single VA medical facility or a consortium of collaborating VA medical facilities. In the latter case, the sites must demonstrate how the resources of participating sites will complement each other and result in significant synergy.

b. **Site Leadership.** Each HCFRC will be led by a Director who is a clinician with at least a 5/8<sup>th</sup>'s salaried position in a VA medical facility. Other core personnel positions will be determined by the strategic and operational plans of the center(s). If several facilities are joining to submit one proposal, one VA medical center must be designated as the lead facility with one Center Director for the HCFRC. The lead facility will be responsible for disbursing funds to others in the consortium. All funding requests must be combined on the budget sheets in Attachment D.

c. **Focus Areas.** The HCFRC program is designed to produce high quality, tangible, and useful products with direct and immediate applicability to all VA facilities involved in hepatitis C screening, testing, care, and prevention. Applications are sought which center on one specific area of focus. While an individual center may be involved in more than one of these areas, demonstration of the capacity to provide outstanding leadership in a specified focus area is required. The essential focus areas of the HCFRC program include:

**(1) Patient Knowledge and Self-management Skill**

(a) This area of focus encompasses the broad range of activities that improve patients' abilities to participate in their own care through increased awareness of hepatitis C transmission, natural history, and treatment. Beyond the traditional concepts of patient education, the practice of providing training and support in self-management skills and health promotion helps patients to take on a more active role in their treatment and management of their hepatitis C, and to adopt changes necessary for effective coping with hepatitis C. The focus may include areas such as: knowledge of hepatitis C transmission and natural history, adherence to treatment recommendations, life-style modifications, symptom management, and improving communications with health care providers.

(b) Effective products from this area of focus will lead to:

1. Greater awareness of hepatitis C in veteran populations;
2. More effective screening and testing programs;
3. More at-risk patients self referring for testing;
4. More infected patients seeking information about treatment;
5. More success in completing a course of treatment; and
6. Fewer patients with adverse health consequences from hepatitis C.

**(2) Disease Prevention and Behavior Modification**

(a) A second area of patient-oriented focus involves the behavioral factors relating to both primary and secondary disease prevention. Primary prevention will be defined as the prevention of new cases of hepatitis C and secondary prevention will be directed towards the prevention of complications from hepatitis C infections. Behavior change related to primary prevention activities would focus on those activities resulting in transmission of hepatitis C, predominantly needle use. Work in this area will include the development and "marketing" of effective risk reduction programs, as well as models of how to translate the findings of prevention research into routine clinical practice in VA. These programs would potentially target infected populations, as well as populations that are uninfected but at-risk in prevention models that will help them reduce the risk of transmitting or acquiring hepatitis C. Behavior change related to secondary prevention of complications from hepatitis C infections would include both patient-directed (such as alcohol abstinence) and care provision (such as vaccination) activities.

(b) Effective products from this area of focus will lead to:

1. Fewer new cases of hepatitis C among veterans and in their communities;
2. Decrease in behaviors, particularly related to alcohol consumption, which accelerate disease progression in hepatitis C-infected veterans;
3. Greater use of preventive measures such as vaccination, cancer screening, etc.; and

4. Fewer patients with hepatitis C who progress to end stage liver disease.

### (3) **Provider Support and Skill Development**

(a) Centers with this area of focus will serve as leaders in the effort to ensure that all VA clinicians have access to current and accurate information regarding hepatitis C diagnosis and treatment. In addition to providing appropriate technical and scientific information, this area of focus incorporates the concept that effective clinicians require specific skills, as well as knowledge. Relevant skills in the field of hepatitis C might include: interpretation of patient data (diagnostic tests, histopathology results, etc.), effective counseling and communication skills, and data and information management techniques.

(b) Effective products from this area of focus will lead to:

1. Increased skill in identifying patients at risk for hepatitis C infection;
2. Improved ability to counsel patients about hepatitis C infection;
3. Improved skills in interpreting data related to patient management;
4. Greater awareness of important developments in hepatitis C care;
5. More successful management of medication toxicity;
6. Improved ability to manage complications of hepatitis C infection; and
7. Fewer adverse medical outcomes.

### (4) **Development of Best Practice Models**

(a) Centers will serve as “laboratories” for the creation of new and innovative systems and processes of care which enhance the efficiency, consistency, and quality of hepatitis C care to veterans. Areas which might be included within this focus are things such as: the structure of hepatitis C clinics; the relationship between specialists and primary care providers; the use of ancillary services to improve treatment outcomes; programs to improve follow-up and continuity of care; use of community-based and home care services; and telemedicine systems. With appropriate evaluation, these will become best practice models to be replicated in other VA facilities.

(b) Effective products from this area of focus will lead to:

1. Development of more effective interdisciplinary approaches to care delivery;
2. More effective use of limited health care resources;
3. Decreased variation in quality of care amongst different facilities; and
4. Less loss to follow-up and improved continuity of care.

**5. RELATIONSHIP TO RESEARCH:** The focus of this program is the enhancement of patient care. However, in the field of hepatitis C, research may lead to rapid changes and improvement in clinical care. Therefore, it is consistent with the goals of this program for



b. The second level of review will be an internal review by the Office of Public Health and Environmental Hazards, led by the Chief Consultant, Public Health Strategic Healthcare Group. The purpose of the second level review will be to choose a group of sites whose strategic plans are complementary rather than redundant. This review will compare the scores of applications in each of the focus areas described in paragraph 4, and consider the highest scoring application(s) in each area for funding. If there are no applications of sufficient merit in a given focus area, no awards may be made for that area. Similarly, if two applications in a given area are of sufficiently high merit and are felt to be complementary, more than one award in a given focus area will be considered.

**8. ANNUAL PROGRESS REVIEW:** Each funded Center will be asked to submit an annual budget and performance report to VHA Headquarters. Performance measures will include:

- a. Status of implementation of the strategic plan;
- b. Description of projects underway;
- c. Evidence of local and national impact;
- d. Contributions to published literature;
- e. Detailed listing of all funds provided to and all funds expended by the HCFRC; and
- f. Success in collaboration and communications with other HCFRC's and VHA Headquarters.

**9. ROLE OF VHA HEADQUARTERS AND RELATIONSHIP TO OTHER HCFRCs:**

The combined HCFRCs, each specializing in a specific focus area, will represent important VA leadership in hepatitis C. Considerable overlap is expected among the areas of expertise, products and leadership of the HCFRCs. The HCFRCs will be required to work collaboratively to provide VHA with the highest quality programs and services in hepatitis C. The HCFRC program will be administered by the Office of Public Health and Environmental Hazards, Public Health Strategic Health Care Group. HCFRCs will be evaluated on the success in collaboration and communications with other HCFRCs and VHA Headquarters.

**10. VHA-WIDE DISSEMINATION OF HCFRC PRODUCTS AND/OR FINDINGS, BEST PRACTICES:**

It is the intent of this solicitation to create HCFRCs which will, in many ways, improve every VA medical facility's capacity to maximize hepatitis C screening, counseling, testing, treatment, and prevention efforts. Thus, HCFRCs will be required to work with the Office of Public Health and Environmental Hazards to disseminate HCFRC products, programs, and/or activities and/or materials. *NOTE: Failure to meet this requirement is sufficient cause for funding to be discontinued.*

**11. RESPONSIBLE OFFICE:** The Public Health Strategic Healthcare Group, Office of Public Health and Environmental Hazards (13B) is responsible for the contents of this notice. Inquiries regarding this solicitation should be directed to: Office of Public Health and Environmental Hazards (13B), Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420.

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**12. RESCISSION:** This VHA Notice expires June 30, 2006.

S/ Frances Murphy, M.D.  
Thomas L. Garthwaite, M.D.  
Under Secretary for Health

Attachments

DISTRIBUTION: CO: E-mailed 6/13/2001  
FLD: VISN, MA, DO, OC, OCRO, and 200 – E-mailed 6/13/2001

**ATTACHMENT A**

**INSTRUCTIONS FOR THE SUBMISSION OF A LETTER OF INTENT (LOI)**

**1. Text.** The text of the LOI is limited to two single-spaced, typed pages using font Times New Roman 12. The text of the letter is to follow the format and incorporate the subheadings specified in the following.

a. **Title of the Hepatitis C Field-based Resource Center (HCFRC).**

b. **Director.** Name, location and contact information (telephone number and e-mail address) for the proposed HCFRC Director. Include a current curriculum vitae.

c. **Center description.** Briefly describe the proposed HCFRC in terms of population served, existing resources, key affiliations, and ability to respond to the goals of the HCFRC program.

d. **Proposed area(s) of focus** (see par. 4 of Veterans Health Administration (VHA) Notice 2001-02).

e. **Reviewers.** The names and contact information for two individuals not affiliated with the proposed center who would be potential reviewers of a full application.

**2. Submission.** Submit the LOI electronically using Microsoft Word, as well as a hard copy by mail to VHA Headquarters as follows: **NOTE:** *Call 202-273-8567 for the electronic address.*

Office of Public Health and Environmental Hazards (13B)  
Department of Veterans Affairs  
810 Vermont Avenue, NW  
Washington, DC 20420

**3. Due date.** July 15, 2001.

**4. Review process.** The LOI will be reviewed for the importance of the proposed center to the goals of the program, responsiveness to the solicitation, and potential of the center to substantially advance the field of hepatitis C virus care. Each applicant will receive notification by August 1, 2001, indicating whether or not the submission of a full proposal is invited.

**NOTE:** *Only invited full proposals will be reviewed.*



**ATTACHMENT B**

**INSTRUCTIONS FOR APPLICATIONS**

1. Submit three copies of the application, as well as an electronic copy via e-mail to: **NOTE:** Call 202-273-8567 for the electronic address.

Office of Public Health and Environmental Hazards (13B)  
Department of Veterans Affairs  
810 Vermont Avenue, NW  
Washington, DC 20420

a. The electronic submissions must be in Microsoft Word and Excel.

b. Type material single-spaced, leaving a 1-inch margin at each edge of each sheet. Type the name of the proposed Hepatitis C Field-based Resource Center (HCFRC) Director in the lower right portion of each number page. Use Times New Roman font size 12 on 8 ½ X 11 pages.

c. The budget sheets may be submitted on legal paper.

2. Applications should conform to a standardized format as outlined in the following paragraph.

3. If an area to be discussed does not fit logically into the following titles provided, add this information as an Appendix. Each Center may submit up to two reprints representing their most important recent work.

4. **Contents of the application.** The narrative portion should conform to the following outline of content areas.

a. **Cover page.** Include the HCFRC title, name and address of the HCFRC Director, name and facility number of the Department of Veterans Affairs (VA) medical center(s) involved, total first year budget.

b. **Background.** Address the history and background of the VA medical center's specific interest in and contribution to hepatitis C care. This discussion should acquaint the reviewer with current activities in treatment and research, particularly as they relate to chosen area(s) of focus. **NOTE:** *The maximum length for this section is two pages.*

c. **Personnel.** Provide curriculum vitae or bio-sketch for HCFRC Director and all named personnel, including the individual responsible for operations and fiscal oversight if other than the Director. Any currently active clinicians or researcher who will contribute to the HCFRC activities should be named regardless of request for salary support. Administrative and technical personnel may be listed by position (to be named). For each named individual, list the name, academic title (when appropriate), VA title, VA employment status, and any key affiliations.

d. **Resources and environment.** Describe the facilities available. Distinguish between those resources that are currently in place and those that must be added to fulfill the Center's

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mission. Describe other ongoing programs at the medical center and explain how the Center will enhance and support these programs, and vice versa. **NOTE:** *The maximum length for this section is one page.*

e. **Strategic plan.** Describe in up to fifteen pages, the:

(1) Proposed areas(s) of focus for the HCFRC chosen from among those identified in paragraph 4 of Veterans Health Administration (VHA) Notice 2001-02.

(2) Specific projects proposed including sufficient background and rationale to evaluate their potential value to VHA.

(3) Products, programs, or services to be created and their potential for widespread utility and applicability in VHA.

(4) Implementation plans.

(5) Plans for evaluating the utility of these projects and products.

**NOTE:** *The strategic plan should include estimates of time required for preparatory work, program and/or product development, evaluation and implementation (i.e., a timeline for completion of all projects proposed).*

f. **Operational plan.** Describe the administrative and professional structures needed to accomplish the strategic plan. Describe the proposed systems for financial administration and accounting. Describe how the Center's organization will relate to other organizational structures within and outside the medical facility. **NOTE:** *The maximum length for this section is four pages.*

g. **Community Advisory Board.** Describe how the Center will obtain community input and the composition of or specific plans for a community advisory board. **NOTE:** *The maximum length for this section is one page.*

h. **Budget.** All funding requested for the HCFRC must be indicated on these sheets. **NOTE:** *See Attachment D for an example of the budget sheets to be submitted.*

i. **Appendixes.** The following may be included as appendixes:

(1) Letters of support and endorsement;

(2) Reprints of recent publications (no more than two); and

(3) Other relevant information.

ATTACHMENT C

INSTRUCTION FOR COMPLETING BUDGET FORMS

- 1. Budget template.** In order to facilitate review of the application, a formatted budget template will be supplied electronically to each applicant who is invited to submit a full application. If this form does not address all the budget items one would like, submit additional information in addition to these forms.
- 2. Each item in the budget must be justified.** Additional pages may be used to justify the budget. Be clear as to why, what is requested is needed, and validate the cost figures provided.
- 3. This form is EXCEL version 97 SR-2.** By using this form, the formulas are imbedded; hence final calculations are automatically completed. **NOTE:** *If you choose not to use the EXCEL form, submit a form that is very similar in format and content to the example provided.*
- 4. The spreadsheet is a template for applicants.** Maximum funding levels for individual categories are given in the solicitation. Other figures on this spreadsheet are placeholders for applicants to work with. The numbers in red are maximum numbers indicating these figures may not be exceeded. In other cases, names and numbers are in black and are "typical" items, personnel and costs that might be entered. However, these are only examples and the personnel required by the strategic plan for the HCFRC, should be listed. The maximum which may be requested in the Fiscal Year (FY) 2002 year is \$1,000,000 in Medical Care funds. The recurring costs may not exceed \$500,000 in subsequent years. Up to five full-time employee equivalent (FTEE) may be requested to initiate this Center. **NOTE:** *Continuation of funding is based upon criteria identified in the solicitation and is dependent upon availability of funds.*
- 5. Personnel information.** There are two parts of the Personnel information requested. The Personnel noted on the top of the form is to indicate those who will receive any salary support from the HCFRC budget. At the bottom of this form, indicate all those who will contribute effort to the HCFRC regardless of request for salary support.
- 6. Prepare your budget as a full-year budget.** It is anticipated that funds for successful applications will be available in 2<sup>nd</sup> Quarter of FY 2002. Inflationary increases have not been allowed for centers of this type. Do not increase the FY 2002, FY 2003, FY 2004, FY 2005, or FY 2006 year budgets calculating any inflationary increases.
- 7. Do not request any travel funds or equipment funds except in the FY 2002 year.** In VHA Headquarters, these funds are considered by a separate Committee. The HCFRC Directors will be contacted so that plans might be made for their travel and equipment replacement and/or repairs needed in future years.



**ATTACHMENT D**

**SAMPLE BUDGET TEMPLATE**

An Excel file with embedded formulae is available electronically. Request it by calling 202-273-8567.