



Clinical Research Centers of Excellence RFP Questions & Answers

The following questions and answers are to help provide guidance to those interested in responding to the Clinical Research Centers of Excellence (CRCoE) request for proposals. Answers are based, in part, on a national conference call held by Dr. Nelda Wray on Sept. 24, 2003 in which there were over 70 participants. Additionally, the following primarily addresses items related to the Letter of Intent and/or overall program scope. Matters specifically related to the national network and/or off-site training elements of the program will be addressed in more detail after CRCoEs are selected. Further questions should be directed to Grant Huang, MPH, Ph.D. at grant.huang@hq.med.va.gov or at (202) 254-0252.

1. Can a single site submit multiple proposals?

Multiple proposals from a single site would most likely reduce each of the application's chances of being successful and **is discouraged**.

2. Can multiple groups/sites within a given geographical location submit a single proposal?

Yes. Collaborations are encouraged.

3. Can the proposed CRCoE have a primary area of expertise/research?

Yes. However, successful applications will demonstrate the CRCoE's ability to meet program goals, especially in relation to training Clinical Scholars across a broad range of subspecialties.

4. Is the CRCoE program for clinicians who want to do "bench" (laboratory) based training?

No. However, an ORD "Bench to Bedside" program is planned for the future. This program will focus more on those investigators interested in translating bench findings into clinical applications.

5. Is the program only for MDs who wish to receive training?

MDs selected as CRCoE Clinical Scholars will receive salary support and are eligible for pilot project funds. However, waivers for Ph.D. clinicians interested in CRCoE activities (as Clinical Scholars) will be considered.

6. Can Ph.D.s apply as Principal Investigators (CRCoE Directors)?

No. Given the scope of CRCoE activities, a senior level MD with experience in mentoring and directing clinical research training across all clinical subspecialties would be best qualified to serve as a director. However, Ph.D.s may be involved as CRCoE mentors.

7. Can the PI be someone without formal training in research methodology?

The strongest application will be from a PI who is an MD with experience and training in research methodology and is able to help mentor young clinical researchers across a broad range of subspecialties. If a PI does not have training in research methodology, it is strongly suggested that such an expert be included as a Co-PI.

8. Does the PI/Director have to be a 5/8th FTEE VA employee?

Yes. However, a waiver of the 5/8th FTEE requirement may be submitted. This waiver should clearly state how the PI/Director would ensure that the CRCoE maintains a VA identity.

9. Does a Co-PI have to be a VA employee?

Yes. However, waivers may be submitted that justify the inclusion of a non-VA based Co-PI.

10. Can individuals with no Masters degree in the core disciplines of clinical research (e.g., Epidemiology, Statistics, etc.) be mentors?

Yes, although the explicit qualifications and significant experience of these individuals to provide mentoring at the level required must be clearly indicated.

11. Can a mentor be an individual at the local university (but not in VA)?

Mentors above and beyond the 2 FTEE methodologists serving as part of the Core Facility, **do not** have to be VA employees. However, these individuals will not receive any salary support from CRCoE awards.

12. Can methodologists to be recruited as part of the CRCoE be initially from outside the VA?

Yes. It assumed that once hired as part of the CRCoE Core Facility, the methodologists will fully commit efforts to the CRCoE and related activities.

13. Is there flexibility on having more/less than 6 members on the steering committee?

Yes. If the steering committee will be more/less than 6 members, a clear justification for the suggested number and actual members is required.

14. How are Clinical Scholars to be selected?

Clinical Scholars are to be **selected locally** at the discretion of the respective CRCoE (i.e., CRCoE Steering Committee). ORD will primarily “sign-off” on those individuals submitted by the CRCoE for Clinical Scholar positions.

15. Can awarded funds be used to pay tuition/fees related to clinical research training at a local university?

No.

16. How many CRCoEs are expected to be funded?

Depending on budget and the number of applications, it is anticipated that **between 10-15** CRCoEs will be funded. More importantly, it is intended that enough CRCoEs will be funded to form a national network for clinical research training.

17. What are the key dates for the CRCoE Program?

Letter of Intent (LOI) due **Oct 21, 2003.**

Full proposals due **Feb 2, 2004.**

Earliest funding date expected in **June/July 2004.**