Amendment #3
to RFP-NIH-NIAID-DMID-01-16

"Hepatitis C: Recovery Research Network"

Amendment to Solicitation No.:	NIH-NIAID-DMID-01-16
Amendment No.:	3
Amendment Date:	October 6 , 2000
RFP Issue Date:	July 26, 2000
Issued By:	Barbara A. Shadrick Senior Contracting Officer NIH/NIAID Contract Management Branch 6700-B Rockledge Drive Room 2230, MSC 7612 Bethesda, Maryland 20892-7612
Point of Contact:	Janet M. Mattson, Contract Specialist
Name and Address of Offeror:	To All Offerors

The above referenced solicitation is hereby amended as follows to respond to questions presented by recipients of this RFP:

Question 1. The RFP calls for development of appropriate data bases and data analysis, including the capacity to integrate multiple centers in data collection, provide data entry and system access at cooperating clinical and research sites, etc. At some point in this process, the idea has emerged that the resources of organizations already contracted (by NIAID) to perform this sort of study data management and/or specimen repository services may be made available for the purposes of the HCV Recovery Network. (i.e., that a company with existing NIAID contracts, as an example, EMMES Corporation, may be contracted to provide this service). Is this true? We are in the process of selecting optimal strategies to perform these objectives, and clearly need to know if a vision for this aspect of the project already exists at NIAID/DMID.

Answer. NIAID and other NIH Institutes have multiple approaches to handling data management and repository functions as well as providing assistance with respect to statistics, protocol design, development of case report forms, and logistics. For this RFP (Hepatitis C: Recovery Research Network) the Government intends that Offerors include in their proposal and provide the capability for such activities in the Proposal. It is not the Government's intent for the Offeror to assume that such activities will be performed by existing contracts.

To assist potential Offerors, we provide below a compilation of existing resources including a brief description, the name of the responsible organization, and principal investigator's name and contact points.

The Division of Microbiology and Infectious Diseases (DMID) uses the contract mechanisms to fund such activities. Sometimes, as is the case in this RFP, DMID includes these activities in the parent contract, e.g., the Collaborative Antiviral Studies Group (Dr. Richard Whitley, Ph.: 205-934-5316, e-mail pedp070@uabdpo.dpo.uab.edu) and the Mycoses Study Group. DMID also funds individual contracts to provide these functions to other clinical trial efforts, e.g., the Vaccine and Treatment Evaluation Units, supported by the Division. Current contractors include the EMMES Corporation (P.I., Dr. Mark Wolff, Ph.: 301-299-8655, e-mail: mwolff@emmes.com) for study design, protocol development, statistical and data

management functions, logistical coordination and statistical analyses. The EMMES contract is currently being recompeted. McKesson Bioservices HBOC (P.I., Mr. Dennis Beardsley, Ph.: 240-684-0551, ext. 226, e-mail: dennis.beardsley@mckessonbio.com) handles drug repository and shipment functions. DMID does not currently fund a separate specimen repository. In addition, DMID recently contracted with Family Health International (P.I., Dr. Kenneth Schulz, Ph.: 919-544-7040, ext. 542, e-mail: kschulz@fhi.org) to assist with DMID's international trials/studies in areas of site evaluation and training, logistical assistance, statistical and epidemiological support for design and analysis, and data collection, management and analyses.

The Division of Acquired Immunodeficiency Syndromes (AIDS) uses the cooperative agreement mechanism to support most of its clinical trial efforts. The Harvard School of Public Health provides support for the AIDS Adult Clinical Trial Group (AACTG) and the Pediatric Clinical Trial Group (PACTG) both of which perform treatment trials. The principal investigators (PIs) are respectively, Dr. Victor Degruttola (Ph.: 617-432-2820, e-mail: victor@sdac.harvard.edu) and Dr. Michael Hughes (Ph.: 716-432-3161, E-mail: mhughes@sdac.harvard.edu). Both groups provide statistical expertise, support and leadership, as well as data management expertise and support. Data management expertise and support is handled via a subcontract to Frontier Science and Technology Research Foundation (PI: Mr. Greg Pavlov, Ph.: 716-834-0900, e-mail: pavlov@fstrf.org) in Amherst, NY. FSTRF designed the distributed data entry system.

Statistics and data management activities for the HIV Vaccine Trial Network (HVTN) and the HIV Prevention Trial Network (HPTN) take place via the Fred Hutchison Cancer Research Center (PI: Dr. Steven Self, Ph.: 206-667-4944, e-mail: steve.self@hivnet.fhcrc.org). This group uses a FAX-based data entry and management system, provides statistical support, and case report from development. In addition, Family Health International (P.I. Dr. Willard Cates, Ph.:914-544-7040, e-mail: wcates@fhi.org) provides support in terms of protocol development, and multi-site management.

DAIDS also funds a large specimen repository contract at BBI Biotech Research Laboratories (PI: Dr. Mark Cosentino, Ph.:301-208-8100, e-mail: mcosentino@bbii.com). It receives, catalogues, ships, and maintains inventory on specimens. See http://www.niaid.nih.gov/reposit/over.htm for more information and http://www.niaid.nih.gov/contract/archive/9902rfp.htm for a copy of the RFP. In addition, Frontier Science and Technology Research Foundation (see above) was funded to develop a new laboratory and data management system for accrual, tracking, and use of specimens; it allows for electronic submission of laboratory results to the repository.

Question 2. In section L, page 31, of the RFP, the Estimate of Effort is stated to be approximately 4,190 hours/year. This is equivalent to approximately two (2) FTEs. Please explain.

Answer. The 2 FTEs represent an estimate for the level of effort needed by the main contractor presuming that it would primarily cover coordination efforts. In putting together the FTE estimate, the Government assumed that much of the effort would occur via subcontracts and these FTEs were not included in the total. Obviously, there are other ways to arrive at a complete picture of how the study might be performed. Offerors are free to propose their own vision and the effort associated with it.

Except as provided herein, all terms and conditions of this RFP remain unchanged and in full force and effect.

- The hour and date specified for receipt of offers REMAINS: **December 15, 2000, 4:00 PM, EST**.
- Offerors must acknowledge receipt of this Amendment #3, on each copy of the proposal submitted.

Failure to receive your acknowledgment of this amendment may result in the rejection of your offer.

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