

## MORGELLONS

As an independent contractor, and not as an agent of the US Government, the contractor shall provide the following deliverables in accordance with Section 4 of the SOW below :

ITEM	SUPPLIES / SERVICES	QTY / UNIT	UNIT PRICE	EXTENDED PRICE
0001	IRB Clearance	1 job		
0002	Provide database of potential cases (study cohort)	1 job		
0003	Provide database containing all results of clinical evaluations.	1 job		
0004	Provide all skin biopsy specimens and fiber samples collected from case-patients.	1 job		
0005	Provide database with denominators for all visits (total and by specialty).	1 job		
Total				

## STATEMENT OF WORK

### 1.0 BACKGROUND

Morgellons is an unexplained and debilitating condition that has emerged as a public health concern. Recently, the Centers for Disease Control and Prevention (CDC) has received an increased number of inquiries from the public, health care providers, public health officials, Congress, and the media regarding this condition. Persons who suffer from this condition report a range of coetaneous symptoms including crawling, biting and stinging sensations; granules, threads or black speck-like materials on or beneath the skin; and/or skin lesions (e.g., rashes or sores) and some sufferers also report systemic manifestations such as fatigue, mental confusion, short term memory loss, joint pain, and changes in vision. Moreover, some who suffer from this condition appear to have substantial morbidity and social dysfunction, which can include decreased work productivity or job loss, total disability, familial estrangement, divorce, loss of child custody, home abandonment, and suicidal ideation.

As of February 2007, approximately 10,000 families had registered with the Morgellon's Research Foundation (MRF) and felt they or a family member met criteria for Morgellons as defined by the MRF. Of the U.S. families in the MRF registry, 24% reside in California with geographic clustering in the San Francisco metropolitan area.

The etiology of this condition is unknown, and the medical community has insufficient information to determine whether persons who identify themselves as having this condition have a common cause for their symptoms or share common risk factors. An epidemiologic investigation is needed to better characterize the

clinical and epidemiologic features of this condition; to generate hypotheses about factors that may cause or contribute to sufferers' symptoms; and to estimate the prevalence of the condition in the population; and to provide information to guide public health recommendations. A contractor is needed who can provide timely services to assist the CDC in the investigation of this emerging public health problem.

## **2.0 DESCRIPTION OF WORK**

The purpose of this project is to:

- 2.1. Describe the clinical and epidemiologic features of persons who have reported themselves as having this unexplained skin condition, including assessing the frequency of co-morbid conditions (e.g., neurocognitive deficits, neurologic conditions, major psychiatric disorders).
- 2.2. Collect information to generate hypotheses about possible risk factors for this condition.
- 2.3. Assess the histopathologic features of the skin condition based on skin biopsies from a sample of affected patients.
- 2.4. Characterize fibers or threads obtained from patients with the condition to determine their potential etiology.
- 2.5. Describe the geographic distribution and estimate rates of illness.
- 2.6. Describe health care utilization among persons with the condition.

## **3.0 MINIMUM VENDOR QUALIFICATIONS**

In order to successfully perform the required services the vendor shall have the following minimum vendor qualifications:

- 3.1. Electronic health records that have been implemented in the organization at least since January 2006.
- 3.2. Ability to conduct electronic queries of medical records, including progress notes, to identify clinical conditions and complaints.
- 3.3 Health maintenance organization with at least 3 million enrollees and coverage of at least 25% of the population in the chosen geographic area.
- 3.4. Location in a geographic area with a large number of suspected cases.

3.5. Experience in conducting clinical and epidemiologic studies.

3.6. Adequate qualified personnel to successfully perform the requested services by the date required.

#### **4.0 DELIVERABLES**

The vendor shall provide the following deliverables to the Project Officer by the date required:

<b><u>Deliverables</u></b>	<b><u>Date Required</u></b>
4.1. IRB Clearance	October 30, 2007
4.2. Database of potential cases (study cohort)	November 30, 2007
4.3. Database containing all results of clinical evaluations, Including recorded histories and physicals, laboratory tests (See Attachment 001 for required laboratory tests), chest x-rays, digital photos, neuorognitive/neuropsychiatric examinations.	March 1, 2008
4.4. All skin biopsy specimens and fiber samples collected from case-patients.	March 1, 2008
4.5. Electronic database containing demographic information, zip code of residence, relevant past health history, such as medications, provider visits, and hospitalizations for cases. Database should include a unique patient identifier to allow linkage of clinical and other test results with demographic, healthcare utilization, and survey data.	April 30, 2008
4.6. Database with denominators for all visits (total and by specialty) and hospitalizations during study period to allow estimation of disease rates in the population.	May 30, 2008

## **5.0 PERIOD OF PERFORMANCE**

The period of performance shall be from the date of the award through May 30, 2008. Upon satisfactory completion of the services and delivery of the goods, the vendor shall submit an invoice to CDC.

## **6.0 Clauses and Provisions**

The Following HHS Clauses applies to this acquisition:

### **6.1 HHSAR 352.270-8b Protection of Human Subjects (Jan 2001)**

(a) The Contractor agrees that the rights and welfare of human subjects involved in research under this contract shall be protected in accordance with 45 CFR Part 46 and with the Contractor's current Assurance of Compliance on file with the Office for Protection from Research Risks (OPRR), National Institutes of Health (NIH). The Contractor further agrees to provide certification at least annually that the Institutional Review Board has reviewed and approved the procedures, which involve human subjects in accordance with 45 CFR Part 46 and the Assurance of Compliance.

(b) The Contractor shall bear full responsibility for the performance of all work and services involving the use of human subjects under this contract in a proper manner and as safely as is feasible. The parties hereto agree that the Contractor retains the right to control and direct the performance of all work under this contract. Nothing in this contract shall be deemed to constitute the Contractor or any subcontractor, agent or employee of the Contractor, or any other person, organization, institution, or group of any kind whatsoever, as the agent or employee of the Government. The Contractor agrees that it has entered into this contract and will discharge its obligations, duties, and undertakings and the work pursuant thereto, whether requiring professional judgment or otherwise, as an independent contractor without imputing liability on the part of the Government for the acts of the Contractor or its employees.

(c) If at any time during the performance of this contract, the Contracting officer determines, in consultation with the OPRR, NIH, that the Contractor is not in compliance with any of the requirements and/or standards stated in paragraphs (a) and (b) above, the Contracting Officer may immediately suspend, in whole or in part, work and further payments under this contract until the Contractor corrects the noncompliance. Notice of the suspension may be communicated by telephone and confirmed in writing. If the Contractor fails to complete corrective action within the period of time designated in the Contracting Officer's written notice of suspension, the Contracting Officer may, in consultation with OPRR, NIH, terminate this contract in a whole or in part, and the Contractor's name may be removed from the list of those contractors with approved Health and Human Services Human Subject Assurances.

(End of clause)

### **6.2. Rights in Data**

All data, information, reports, and other products of this effort are exclusively the property of the federal government and the contractor shall not publish, share, distribute or otherwise release any of this information except with the explicit written permission of the contracting or project officer. Moreover, some of the materials may be designated as national security classified, sensitive but unclassified or other limited use category further restricting its distribution.

### **6.3 FAR Clauses**

The following FAR clauses and provisions apply to this acquisition: The full text of the clauses can be accessed electronically at these addresses: <http://www.acqnet.gov/> and <http://farsite.hill.af.mil/> .

<b>FAR SOURCE</b>	<b>TITLE AND DATE</b>
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52.203-6	Restrictions on Subcontractor Sales to the Government (Sep 2006)
52.204-7	Central Contractor Registration (Jul 2006)
52.204-9	Personal Identity Verification of Contractor Personnel (Nov 2006)
52.207-4	Economic Purchase Quantity - Supplies (Aug 1987)
52.213-1	Fast Payment Procedure (May 2006)
52.213-2	Invoices (Apr 1984)
52.219-6	Notice of Total Business Set-Aside (June 2003)
52.219-14	Limitations on Subcontracting (Dec 1996)
52.222-3	Convict Labor (Jun 2003)
52.222-19	Child Labor-Cooperation with Authorities and Remedies (Jan 2006)
52.222-21	Prohibition of Segregated Facilities (Feb 1999)
52.222-26	Equal Opportunity (Apr 2002)
52.222-35	Equal Opportunity for Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans (Sep 2006)
52.222-36	Affirmative Action for Workers With Disabilities (Jun 1998)
52.222-37	Employment Reports on Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans (Sep 2006)
52.222-41	Service Contract Act of 1965, as Amended (Jul 2005)
52.222-42	Statement of Equivalent Rates for Federal Hires (May 1989)
52.222-43	Fair Labor Standards Act and Service Contract Act - Price Adjustment (Multiple Year and Option Contracts) (Nov 2006)
52.222-44	Fair Labor Standards Act and Service Contract Act - Price Adjustment (Feb 2002)
52.222-47	Service Contract Act (SCA) Minimum Wages and Fringe Benefits (May 1989)
52.223-6	Drug-Free Workplace (May 2001)
52.223-9	Estimate of Percentage of Recovered Material Content for EPA Designated Products (Aug 2000)
52.223-9 Alternate I	Estimate of Percentage of Recovered Material Content for EPA Designated Products - Alternate I (Aug 2000)
52.232-25	Prompt Payment (Oct 2003)
52.232-33	Payment by Electronic Funds Transfer - Central Contractor Registration (Oct 2003)
52.232-36	Payment by Third Party (May 1999)
52.233-3	Protest after Award (Aug 1996)
52.239-1	Privacy or Security Safeguards (Aug 1996)
52.243-1	Changes - Fixed Price (Aug 1987)

**6.4 Provisions:** The following HHS Provision applies to this acquisition:

**Notice to Offerors of Requirements of 45 CFR Part 46, Protection of Human Subjects (Jan. 2001)**

(a) Copies of the Department of Health and Human Services (Department) regulations for the protection of human subjects, 45 CFR Part 46, are available from the Office for Protection from Research Risks (OPRR), National Institutes of Health, Bethesda, Maryland 20892. The regulations provide a systematic means, based on established ethical principles, to safeguard the rights and welfare of individuals who participate as subjects in research activities supported or conducted by the Department.

(b) The regulations define a human subject as a living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual, or identifiable private information. The regulations extend to the use of human organs, tissue, and body fluids from individually identifiable human subjects as well as to graphic, written, or recorded information derived from

individually identifiable human subjects. The use of autopsy materials is governed by applicable State and local law and is not directly regulated by 45 CFR Part 46.

(c) Activities in which the only involvement of human subjects will be in one or more of the categories set forth in 45 CFR 46.101(b)(1-6) are exempt from coverage.

(d) Inappropriate designations of the noninvolvement of human subjects or of exempt categories of research in a project may result in delays in the review of a proposal. The National Institutes of Health will make a final determination of whether the proposed activities are covered by the regulations or are in an exempt category, based on the information provided in the proposal. In doubtful cases, prior consultation with OPRR, (telephone: 301-496-7014), is recommended.

(e) In accordance with 45 CFR Part 46, prospective Contractors being considered for award shall be required to file with OPRR an acceptable Assurance of Compliance with the regulations, specifying review procedures and assigning responsibilities for the protection of human subjects. The initial and continuing review of a research project by an institutional review board shall assure that the rights and welfare of the human subjects involved are adequately protected, that the risks to the subjects are reasonable in relation to the potential benefits, if any, to the subjects and the importance of the knowledge to be gained, and that informed consent will be obtained by methods that are adequate and appropriate. Prospective Contractors proposing research that involves human subjects shall be contacted by OPRR and given detailed instructions for establishing an institutional review board and filing an Assurance of Compliance.

(f) It is recommended that OPRR be consulted for advice or guidance concerning either regulatory requirements or ethical issues pertaining to research involving human subjects.

(End of Provision)

## 6.5 INSTRUCTIONS FOR SUBMISSION OF QUOTES:

- a. Notwithstanding block 10 of SF 18, quoters shall submit their quotes in accordance with the price schedule above on the basis of Firm-Fixed Price for the completion of the tasks/deliverables described in Section B, Price Schedule by **Midnight August 8, 2007**.
- b. Quotes shall be submitted electronically (via e-mail) in MS Word or MS Excel files to [Bbiltz@cdc.gov](mailto:Bbiltz@cdc.gov) . The following format is required as e-mail subject: The Quote No: **2007-Q-09877.KT.doc or xls** (Where “2007-Q-09877” is the respective RFQ No. and “KT” are the first two letters of the respective Contractor's name; and “.doc” and “.xls” are the format extensions.)
- c. In the event there are electronic transmission problems, the following steps shall be taken:
  - i. CDC receives the electronic file timely, but cannot access it. The quoter will be contacted and may be allowed to fax in the portions that cannot be accessed.
  - ii. Quoter sends electronic file, but receives error message indicating e-mail problems at CDC. Fax in a cover sheet indicating transmission difficulties, and the Contract Specialist will contact the Contractor to arrange an alternate method of submission. Quoters are requested not to fax entire proposals to PGO. Facsimile submission shall only be used after contacting the Contract Specialist.
- iv. Quoters are responsible for providing accurate and complete information for evaluation. (Failure to do so may rule the quote unacceptable.) Thus, the quote shall include the following information:
  - i. Vendor’s minimum qualifications IAW/SOW. Qualifications shall include experience of key personnel, as well as, corporate experience for the job. Offerors shall provide a list of same or similar projects performed during the past five years in a format similar to the Experience/Past Performance Matrix provided as an Attachment No. 2 of this RFQ.
  - ii. Past performance is one indicator of the offeror’s ability to perform the contract successfully. The government will evaluate different customers’ opinions about *how well* the quoter has satisfied their requirements. When evaluating past performance, the government may contact

the references provided by the offeror under the Experience/Past Performance matrix or may obtain information from any other source that is available. Offerors are responsible to provide accurate and complete information to verify their past performance. Offerors encouraged to submit past performance evaluations obtained during the past five years.

**6.6 EVALUATION OF QUOTES:** The following evaluation criteria, listed in descending order of importance, apply: (a) Vendor's qualification, (b) Past Performance and (c) Price. (Price is an important factor for award, however, the non-price factors listed above, when combined, are more important than price. CDC reserves the right to award the order to a quoter who may not be the lowest in price.) Award of a firm-fixed price order will be made to a single offeror whose quote, conforming to this RFQ, will be most advantageous to the CDC, price and other factors considered. Award may be made without discussions/negotiations. Quoters are advised to submit their initial quotes in the best favorable terms to the government. Facsimile quotes are not authorized. Technical inquiries shall be e-mailed to [Bbiltz@cdc.gov](mailto:Bbiltz@cdc.gov). Telephone inquiries will not be honored.