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| AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT | | | 1. CONTRACT ID CODE N/A | PAGE OF PAGES 1 5 |
| 2. AMENDMENT/MODIFICATION NO. 0001 | 3. EFFECTIVE DATE April 5, 2013 | 4. REQUISITION/PURCHASE REQ. NO. N/A | 5. PROJECT NO. (If applicable) | |
| 6. ISSUED BY HHS/OS/ASPR/AMCG 330 Independence Avenue, S.W., Room G640 Washington, D.C. 20201 | CODE | 7. ADMINISTERED BY (If other than Item 6) | | CODE |
| 8. NAME AND ADDRESS OF CONTRACTOR (No. Street, County, State and ZIP: Code) | | | () | 9A. AMENDMENT OF SOLICITATION NO. RFP-13-100-SOL-00008 |
| | | | X | 9B. DATED (SEE ITEM 11) April 1, 2013 |
| | | | | 10A. MODIFICATION OF CONTRACT/ORDER NO. |
| | | | | 10B. DATED (SEE ITEM 13) |
| CODE | FACILITY CODE | | | |
| 11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS | | | | |

The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers is not extended.

Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods:

(a) By completing Items 8 and 15, and returning one (1) copy of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATA SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and data specified.

12. ACCOUNTING AND APPROPRIATION DATA (If required)

N/A

13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS,
IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

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| () | A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A. |
| | B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b). |
| | C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF: |
| | D. OTHER (Specify type of modification and authority) |

E. IMPORTANT: Contractor is not, is required to sign this document and return ___ to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)

PURPOSE OF AMENDMENT:

- (1) Provide information on the pre-proposal conference.
- (2) Update Section J and Section L of RFP.
- (3) Provide answers to inquiries received regarding the solicitation.

See page 2

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

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|---|--|---|------------------|
| 15A. NAME AND TITLE OF SIGNER (Type or print) | 16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print) Jason Bell Contracting Officer, AMCG, OS, ASPR, HHS | | |
| 15B. CONTRACTOR/OFFEROR | 15C. DATE SIGNED | 16B. UNITED STATES OF AMERICA | 16C. DATE SIGNED |
| (Signature of person authorized to sign) | | BY  (Signature of Contracting Officer) | 4/5/13 |

The following sections of the RFP are hereby replaced with the following:

SECTION L – INSTRUCTIONS, CONDITIONS AND NOTICES TO OFFERORS

II. GENERAL INSTRUCTIONS

L.1. PACKAGING AND DELIVERY OF PROPOSAL:

- (a) Offerors are invited to submit a proposal in response to this solicitation. All proposals received will become part of the official file.
- (b) The following instructions establish the acceptable minimum requirements for the format and content of proposals.
- (c) The proposal must be signed by an official authorized to bind the Offeror(s) organization and must stipulate that it is predicated upon all the terms and conditions of this RFP.

The proposal must be prepared in two parts: a "Technical Proposal" and a "Business Proposal." Each of the parts shall be separate and complete in itself so that evaluation of one may be accomplished independently of, and concurrently with, evaluation of the other. Proposals will be paginated and shall be legible. Pages shall be numbered consecutively starting with page 1. Pages shall be single-spaced, 8.5 by 11 inch paper of a font no smaller than **11 point**.

L.12. PRE-PROPOSAL CONFERENCE

A pre-proposal conference will be held with prospective Offerors in Washington, DC on **April 17, 2013, from 11:00A.M. – 2:00P.M, EST.** The pre-proposal conference will be held for the purpose of providing information concerning the Government's requirements which may be helpful in the preparation of proposals and for answering any questions which potential Offerors may have regarding this solicitation.

The conference will be held at:

200 Independence Avenue S.W.
Hubert H Humphrey Building, Great Hall
Washington, DC 20201

Please note the following regarding the pre-proposal conference:

1. Enter the Humphrey Building at the Independence Avenue Street entrance.
2. Arrive 30 minutes early to allow time to clear security.
3. Please bring a form of government identification.
4. The nearest metro stop is Federal Center SW.
5. For domestic participants, please email the name of your attendee(s) to **MCM-CSN@hhs.gov** by 5:00 P.M. EST April 12, 2013. Tape recorders and videos are prohibited.

Due to space limitations, each prospective Offeror will be limited to a total of two (2) representatives from their team. Space may be limited and seats will be reserved on a first-come, first-serve basis based on RSVP.

6. The success of this type of conference depends largely on the lead-time available to the Government for research in connection with questions submitted by Offerors. Therefore, you are requested to submit your questions concerning any areas of uncertainty which, in your

opinion, require clarification or correction, in sufficient time to be received **by 5:00 P.M. EST, April 11, 2013**. Questions should be submitted to **MCM-CSN@hhs.gov**. The email subject line should read, "Pre-proposal conference, RFP No. RFP-13-100-SOL-00008."

Presentation material from the conference will be posted on FedBizOpps in an amendment to the BAA following the pre-proposal conference. A set of all questions and answers will be furnished simultaneously to all prospective Offerors whether or not they are in attendance.

Attendance at the pre-proposal conference is encouraged; however, attendance is not a prerequisite for proposal submission and will not be considered a factor in proposal evaluation.

Please also note that due to time requirements for security clearances, foreign nationals will be unable to attend in person. They are permitted to connect remotely using the teleconference and webinar information provided below.

Teleconference Number

Call Phone: 1-877-953-9186 (Toll-Free) or International: +1-517-600-6825 (Toll may apply)

Participant Passcode: 2841001

Webinar (No audio)

Viewing the presentation is via LiveMeeting:

Meeting description: BARDA MCM CSN Pre-proposal conference

Join the webinar by opening the following URL in a web browser:

<http://www.mymeetings.com/nc/join.php?i=SA389407&p=1637990&t=c>

Provide the following info: First Name, Last Name, Email, and Company and check both boxes "Remember me on this computer" and "I have read and agree ...", then select Proceed.

Meeting number: SA389407

Meeting Passcode: 1637990.

The following chart located in the denoted RFP Attachment is hereby updated, as noted in red:

SECTION J – LIST OF ATTACHMENTS

Attachment #1 - 1. Sample Request for Task Order Response 0001

Attachment 1E – Submission Instructions/Evaluation Criteria

Instructions

6) Responses must comply with the page limitations and format specified for each volume. Information submitted beyond limitations identified could negatively impact the evaluation during the rating process. The follow-on paragraphs provide the specific information required for each volume.

| Volume | Format | Page Limitation | Number of Copies |
|---------------------------------|---|--|-------------------------|
| Volume 1 – Technical Submission | MS Word or Adobe Acrobat. Schedules and Gantt charts should be in MS Project or | 20 pages (Excluding the cover page and table of contents) (8.5 x 11 inch paper; no smaller than 11 font) Fold-outs used for charts, tables (May not exceed 11” x 17”; no | One E-mail copy |

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| | equivalent. | smaller than 8 point font) | |
| Volume II – Price Submission | MS Word and Price Data in Excel | 15 pages (8.5 x 11 inch paper or 11x17 fold outs; 11 point font) | One E-mail copy |

Attachment #2. Sample Request for Task Order Response 0002

Attachment 2E – Submission Instructions/Evaluation Criteria

Instructions

6) Responses must comply with the page limitations and format specified for each volume. Information submitted beyond limitations identified could negatively impact the evaluation during the rating process. The follow-on paragraphs provide the specific information required for each volume.

| Volume | Format | Page Limitation | Number of Copies |
|---------------------------------|---|--|------------------|
| Volume I – Technical Submission | MS Word or Adobe Acrobat. Schedules and Gantt charts should be in MS Project or equivalent. | 20 pages (Excluding the cover page and table of contents) (8.5 x 11 inch paper; no smaller than 11 font) Fold-outs used for charts, tables (May not exceed 11” x 17”; no smaller than 8 point font) | One E-mail copy |
| Volume II – Price Submission | MS Word and Price Data in Excel | 15 pages (8.5 x 11 inch paper or 11x17 fold outs; 11 point font) | One E-mail copy |

(End of Summary of Changes to the text of the RFP)

Questions and Answers

The following questions have been submitted by prospective offerors and are addressed below. .

(1) QUESTION:

“The specific question is the mandatory criterion for eligibility:

[POTENTIAL OFFEROR] has not completed a clinical study under an FDA IND application. That probably makes us ineligible if I understand the document correctly. Please advise.”

ANSWER:

If an Offeror has not completed a clinical study under an FDA IND application in the last five years at the time of proposal submission they fail to meet the mandatory criteria for eligibility to receive award as established in the Request for Proposals Section M.1.2. Please be advised that teaming arrangements are encouraged. If a member of an Offeror’s teaming arrangement satisfies the mandatory eligibility criteria, the Offeror’s proposal will qualify for consideration under this solicitation.

(2) QUESTION:

There are apparent discrepancies in the font size restrictions in the document. Is the smallest acceptable font size 10, 11, or 12? Furthermore, is there a separate restriction for the font size contained within tables/charts?

ANSWER:

The smallest font that is allowable in any portion of the proposal is 11 point, with the exception of tables and charts. In tables and charts, the smallest font allowable will be size 8.

These changes are reflected in the above modification to the body of the RFP.