AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID CODE	PAGE OF PAGES
	1 7

2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO. *(If applicable)*
0001	11/16/2017		

6. ISSUED BY	CODE	7. ADMINISTERED BY *(If other than Item 6)*	CODE
National Institutes of Health National Heart, Lung, and Blood Institutes Bethesda MD 20892-7511	IO-NHLBI	National Institutes of Health National Heart, Lung and Blood Institute Bethesda MD 20892-7511	ADM-NHLBI

8. NAME AND ADDRESS OF CONTRACTOR *(No., street, county, State and ZIP Code)*		9A. AMENDMENT OF SOLICITATION NO.
	(x)	HHSN26818HV00005R
	x	9B. DATED *(SEE ITEM 11)* 10/04/2017
		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 extended, ☒ 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 1 copies 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 ACKNOWLEDGEMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE 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 date specified.

12. ACCOUNTING AND APPROPRIATION DATA *(If required)*

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

CHECK ONE	
	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 _____ copies to the issuing office.

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

See Below for Amendment details:

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

15A. NAME AND TITLE OF SIGNER *(Type or print)*		16A. NAME AND TITLE OF CONTRACTING OFFICER *(Type or print)*	
		Janet M. Mattson	
15B. CONTRACTOR/OFFEROR *(Signature of person authorized to sign)*	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA *(Signature of Contracting Officer)*	16C. DATE SIGNED

SOLICITATION: HHSN26818HV00005R

AMENDMENT: One (1)

TITLE: Gene Therapy Resource Program (GTRP)

DATE OF ISSUANCE: November 16, 2017

ISSUED BY:

National Heart, Lung, and Blood Institute, NIH
Office of Acquisitions, OM
6701 Rockledge Drive
Bethesda, Maryland 20892-7902

The above numbered solicitation is amended as set forth below. **The hour and the date specified for receipt of proposals remains unchanged.** All other terms and conditions of the solicitation remain unchanged. Offerors must acknowledge receipt of the amendment prior to the hour and the date specified in the solicitation or as amended, by one of the following methods:

I. By acknowledging receipt of this amendment on each copy of the proposal submitted. **Please note that this is the preferred method.**

II. By separate letter or email which includes a reference to the solicitation and amendment number.

FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF PROPOSALS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR PROPOSAL. If by virtue of this amendment you desire to change a proposal already submitted, such change may be made by letter, provided each letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

PURPOSE: The purpose of this amendment is to: (1) include information on the webinar held on November 21, 2017; (2) include questions from offerors and responses in reference to the solicitation; and (3) remove a FAR cite from the Representations and Certifications in the solicitation.

1. WEBINAR INFORMATION:

GTRP RFP Discussion

Date: Tuesday, November 21, 2017

Time: 12:00 – 3:00 pm, Eastern Standard Time

Join by phone: 1-650-479-3208 Call-in toll number (US/Canada)

Meeting number (access code): 623 714 117

Meeting password: pK7qmsQa

WebEx URL:

https://nih.webex.com/mw3100/mywebex/default.do?service=1&siteurl=nih&nomenu=true&main_url=%2Fmc3100%2Fe.do%3Fsiteurl%3Dnih%26AT%3DMI%26EventID%3D605232537%26UID%3D0%26Host%3DQUhTSwAAAARnyN18x2rsxKOCUy1t1DGEPW_JfFbUhoLnAzP7Pe2DVxOKiy-j-14YVnAUerk4hnE4tOyQvHx80xyhVYrgWBvt0%26FrameSet%3D2%26MTID%3Dm47dfd8956c95b079f256599239204a52

2. QUESTIONS/ANSWERS:

1. *RFP, General:* Will contracts be awarded to just one facility (offeror) per Core?

   Response: A contract in the Core area may be awarded to more than one offeror. Also, an offeror may be awarded a contract in one or more of the Core areas. Hence, each core laboratory (Preclinical Vector, Pharmacology-Toxicology, AAV manufacturing and Lentivirus manufacturing) and the Coordinating Center will be awarded single or multiple contracts. Additional contracts will be written for each task order assigned to the core labs and coordinating center.

2. *RFP, Deliverables:* Deliverables include updating the public and private websites.
   a. Will the websites be provided to the awardee in their entirety, including all source code and databases?

      Response: Yes, code and content from the current website would be provided to the awardee, including databases.

   b. Are the current public and private websites 508 compliant?

      Response: Yes, the current public and private websites are 508 compliant.

   c. Is the security category for the public and private websites to be low or moderate? If moderate, were the current public and private websites constructed for a moderate environment?

      Response: Yes, the security is moderate.

3. *RFP, Task Area C – Clinical Coordinating Center:* Should the CCC budget include clinical trial funding? If so, how much should be budgeted for each year and for how many sites? If providing an amount for clinical trial funding, does this sum include the amount needed for site visits?

   Response: No, clinical trial funding will be awarded on an ad hoc basis via separate task orders.

4. *RFP, pg. 52, Item 17 - Past Performance Information:* It states the offeror shall submit a "list of the last five (5) contracts completed during the past three (3) years and contracts currently being performed." Please confirm the government will allow the inclusion of grants and cooperative agreements in this section.

   Response: The government confirms the inclusion of grants and cooperative agreements are allowed to be listed as part of offeror's past performance information.

5. *RFP, pg. 59, Item 5b:* The RFP requires that offerors must include a plan for sharing model organisms. Will the government remove this requirement for proposals related to Task Area C?

   Response: Yes, the Clinical Coordinating Center will not be required to develop a plan to share model organisms.

6. *RFP, pg. 75, Item 3:* The RFP requires that offerors include a separate section titled 'Vertebrate Animal Section.' Given the scope of work in Task Area C, will the government remove this requirement for Task Area C proposals?

   Response: Yes, Section M.3 does not apply to Task Area C. This is only applicable if vertebrate animals will be utilized and the RFP will be amended accordingly.

7. *Attachment #3, Statement of Work, pg. 4:* Offerors are directed to respond to Task Area A in addition to their proposal for the Clinical Coordinating Center. In accordance with our disclosure statement, the administrative tasks in Task Area A (purchasing, contract management, facilities, and other incidental costs) are incorporated into our overhead rates and cannot be priced separately. Will the government remove the requirement to respond to Task Area A for offerors responding to Task Area C?

   Response: Task Area A is for the administration of work related to the GTRP program as a whole. Tasks that are not necessarily Task Order specific shall be priced. It is understood that some costs are corporate and included in overhead rates.

8. *Attachment #3, Statement of Work, pg. 8:* Is an indication that the Preclinical Vector Core laboratory will provide immunology assays including T and B cell assays. Could these be provided to the other GTRP cores, for example the Pharm Tox core? Could NHLBI describe the envisioned mechanism for obtaining these services?

   Response: Yes, if the Preclinical Vector Core laboratory did not have T and B cell assays it could procure these services via subcontracts, including to other GTRP core laboratories.

9. *Attachment #3, Statement of Work, pg. 12, Item 13:* In addition to confidential information and data from investigators, will other types of data, such as clinical trial data, be managed or stored by the CCC?

   Response: Storage of clinical trial data is not within scope of services for the CCC. Trial data would be limited to budgets and regulatory affairs documentation.

10. *Attachment #3, Statement of Work, pg. 12, Item 16:* It states that the CCC will ensure that each Core Laboratory has up-to-date versions of all required certifications, inspections, and assurances, and ensure that these are available for review during any site visit by the NHLBI or any other oversight authorities. Is it the responsibility of the CCC to perform formal audits of the Core laboratory facilities?

    Response: No, the CCC will not be required to conduct formal audits of the Core labs.

11. *Attachment #3, Statement of Work, pg. 13, Item 17:* It states that the CCC will ensure that any site approved to receive funding assistance from the GTRP for a gene therapy clinical trial has all the required certifications and approvals necessary for human subject research in gene transfer trials in place prior to the distribution of any funds to the site and ensure that during the course of the conduct of the clinical trial these various certifications and approvals are updated and remain valid. Is it the responsibility of the CCC to perform formal audits of the clinical trial sites or site initiation and periodic site visits as stated in number 24 f?

    Response: No, if site visits are necessary, the CCC will not be required to perform formal audits during the visits of the clinical trial sites.

12. *Attachment #3, Statement of Work, pg. 13, Item 20:* Task Area C – Clinical Coordinating Center indicates that the CCC is to "manage travel-related expense reimbursements" for Steering Committee members. The uniform cost assumptions matrix for the laboratories includes travel assumptions for Steering Committee meetings. Please clarify whether the CCC will be responsible for the travel costs of laboratory staff attending Steering Committee meetings, or whether the laboratories will budget for travel costs.

Response: No, the CCC will not be responsible for the travel costs of laboratory staff attending Steering Committee meetings. Core laboratory staff have their own travel budgets independent of the CCC.

Statement of Work (SOW) p13 item 20 is revised:

20. Manage travel-related expense reimbursements (airfare, and the standard government *per diem*, hotel stays if needed, and honoraria payments as applicable) for SC members~~, SRB members~~ attending meetings, site visits, or participating in meetings held by teleconference.

It now reads as follows:

20. Manage travel-related expense reimbursements (airfare, and the standard government per diem, hotel stays if needed, and honoraria payments as applicable) for SC members attending meetings, site visits, or participating in meetings held by teleconference.

13. *Attachment #3, Statement of Work, pg. 13, Item 20:* Task Area C also indicates that there may be travel-related expense reimbursements for Scientific Review Board (SRB) members. Please indicate whether SRB members are likely to travel for meetings. If so, how often and to what location?

Response: SRB members are not likely to travel for GTRP meetings and the RFP is amended to reflect this.

14. *Attachment #3, Statement of Work, pg. 13, Item 20:* How much are the honoraria for SRB and DSMB members? For the SRB members, will the honoraria be paid per review session, or per review of each RSA?

Response: The honorarium is set at $200 per meeting or session. Typically, each RSA requires only one session for review.

15. *Attachment #3, Statement of Work, pg. 20, Item 8:* Please expand or provide examples of the other types of data bases that might need to be interfaced? Would this be within GTRP, or more broadly?

Response: If necessary, the other types of data that may need to be interfaced would be from standard sources (e.g., ORACLE or SQL).

16. *Attachment #3, Statement of Work, pg. 20, Item 15:* Is the reference to item 13 correct?

Response: This was a typo and the reference to item 13 is incorrect on page 20 and 25 and has been deleted. The RFP is amended accordingly.

SOW pg. 20 and 25 reference to item 13 is removed:

15. Provide evidence of institutional commitment to this program. Provide evidence of commitment to adhere to the Data, Data Rights, Patents, and Copyrights provisions. ~~spelled out in item (13) above.~~

It now reads as follows:

15. Provide evidence of institutional commitment to this program. Provide evidence of commitment to adhere to the Data, Data Rights, Patents, and Copyrights provisions.

3. SECTION J – Attachment 4 – SECTION K - REPRESENTATIONS, CERTIFICATIONS, AND OTHER STATEMENTS OF OFFERORS:

The following Clause has been deleted from Section K on Page 3 of 13:

(xvi) **52.222-57 Representation Regarding Compliance with Labor Laws (Executive Order 13673).**

For your information: On March 27, 2017, Public Law 115–11 disapproved the rule under the Congressional Review Act. Therefore, by law, the rule has no force or effect, including the FAR 52.222–60 clause. Also on March 27, 2017, E.O. 13782, Revocation of Federal Contracting Executive Orders, rescinded the E.O.s that originally authorized the rule.

END OF AMENDMENT