## AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

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<th>1. CONTRACT ID CODE</th>
<th>2. AMENDMENT/MODIFICATION NO.</th>
<th>3. EFFECTIVE DATE</th>
<th>4. REQUISITION/PURCHASE REQ. NO.</th>
<th>5. PROJECT NO. (If applicable)</th>
<th>PAGE 1 OF PAGES 14</th>
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<td>September 19, 2018</td>
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6. ISSUED BY CODE

National Institutes of Health
Eunice Kennedy Shriver National Institute of Child Health and Human Development
Acquisition Services Branch
6710B, Rockledge Drive
BETHESDA MD 20892-7510

7. ADMINISTERED BY (If other than Item 5) CODE

TO ALL POTENTIAL OFFERORS


9B. DATED (SEE ITEM 11)
August 23, 2018

10A. MODIFICATION OF CONTRACT/ORDER NO. -

10B. DATED (SEE ITEM 13)

### 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 __ 1___ copy of the amendment in your business proposal;
(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 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)

A. THIS CHANGE ORDER IS ISSUED PURSUANT TO FAR 52.243-2. 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) and Contract ARTICLE B.4.

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 _ 1 _ copy in your business proposal to the issuing office.

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

**PURPOSE:**
1) extend the deadline for receipt of proposals through the NIH electronic Contract Proposal Submission (eCPS) Website;
2) to provide responses to questions from Offerors and
3) to revise SECTION B, ARTICLE B.5. ADVANCE UNDERSTANDINGS of the RFP.

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.

15A. NAME AND TITLE OF SIGNER (Type or print)
Maxwell Kimpson, Contracting Officer
NIH, NICHD, QA, Acquisition Services Branch

16A. NAME AND TITLE OF CONTRACTING OFFICER
Maxwell Kimpson, Contracting Officer
NIH, NICHD, QA, Acquisition Services Branch

15B. CONTRACTOR/OFFEROR

BY ______________________________________________
(Signature of person authorized to sign)

15C. DATE SIGNED

16B. UNITED STATES OF AMERICA

BY Maxwell J. Kimpson - S
Date: 2018.09.19 17:03:09 -04'00'

(Signature of Contracting Officer)

16C. DATE SIGNED
As a result of this Amendment, RFP No. NIH-NIDDK-KUH-2019-2 is amended as follows:

Page 1 of the RFP has been revised to incorporate the following changes:

Item 8. -- Proposals for furnishing the supplies and/or services in THE SCHEDULE will be received at the place specified in, and in the number of copies specified in Attachment 1, "Packaging and Delivery of the Proposal," until 3:00 p.m. ET local time on Friday, October 5, 2018. Offers will be valid for 120 days unless a different period is specified by the offeror on the Attachment entitled, “Proposal Summary and Data Record, NIH 2043.

SECTION B, ARTICLE B.5. ADVANCE UNDERSTANDINGS has been revised to add (a) (Indirect Costs (for combined) and (b) (Indirect Costs (separate) given below, either one of which as applicable will be incorporated into the awarded contract:

a. Indirect Costs (for combined)

1. In no event shall the final amount reimbursable for indirect costs exceed a ceiling of ____ % of ____.

2. The Government is not obligated to pay any additional amount should the final indirect cost rates exceed these negotiated ceiling rates. In the event that the final indirect cost rates are less than these negotiated ceiling rates, the Government's obligation shall be reduced to conform to the lower rate. Any costs over and above this cost ceiling shall not be reimbursed under this contract or any other Government contract, grant, or cooperative agreement.

Or

b. Indirect Costs (separate)

1. In no event shall the final amount reimbursable for Overhead exceed a ceiling of ____ % of ____ . In no event shall the final amount reimbursable for General and Administrative expense exceed a ceiling of ____ % of ____.

2. The Government is not obligated to pay any additional amount should the final indirect cost rates exceed these negotiated ceiling rates. In the event that the final indirect cost rates are less than these negotiated ceiling rates, the Government's obligation shall be reduced to conform to the lower rate. Any costs over and above this cost ceiling shall not be reimbursed under this contract or any other Government contract, grant, or cooperative agreement.

3. The Contractor shall complete all work in accordance with the Statement of Work, terms and conditions of this contract.
Responses to Questions from Offerors

1. Page 132 of the RFP states that full CVs should be provided for key personnel, biographical sketches for all other named staff, and resumes for EEP members. We have several questions in this area. First, are “biographical sketches” the same as traditional biosketches used for grant applications? Second, although the NIH guidelines for CVs does not include a page limit, the RFP limits CVs to 5 pages. Given that the current limit for biosketches is 5 pages, we are wondering whether the term CVs as referred to in the RFP are identical to biosketches? Third, are resumes different from biosketches, and, if so, how?

Response: Offerors may submit resumes, CVs or biosketches as long as each one does not exceed 5 pages and adheres to the recommended proposal formatting instructions.

2. The RFP states that the current contractors were awarded $8.53M, but according to usaspending.gov, they have been allocated approximately $12.9M during the course of the contract (of which $10.8M has been obligated). What is the source of this difference? Does it represent supplemental appropriations for additional tasks? Does any part of the difference in reimbursement (between the amount allocated and the amount awarded as per the RFP) represent the costs of the Coordinating Center in fulfilling data requests or SAF preparation?

Response: This contract was awarded for $8,530,144. The total obligated amount is $10,886,968. The Government added funds during the period of performance of the contract to address NIDDK programmatic needs and not for fulfilling additional data requests or SAF preparation. The Government recommends that Offerors use the guidance provided for estimated labor hours on the RFP to prepare their proposals.

3. How many less-than-two-hour data requests have the current contractors received since the inception of the contract? How many complex or greater-than-two-hour requests have been received since contract inception?

Response: For the reporting period February 8, 2017- Feb 7, 2018, there were 113 two-hour requests, 40 simple requests, and 13 greater than two-hour requests. The Government does not have the information regarding the total number of requests since the inception of the contract because this was the first year queries were tracked in an itemized fashion. The Government recommends offerors to use the following projections for budget purposes: 150 two-hour requests, 50 simple requests and 30 greater than two-hour requests per year.
4. The way that the RFP is written suggests that the Contractor is expected to handle a maximum number of each type of data requests (e.g., from the renal community, government, complex, and SAF). If the number of requests exceeds this number, will the contractor receive reimbursement from the government?

Response: Once the maximum limit is reached for each type of data requests (see SOW and response to Question 3), the Contractor must notify the NIDDK Contracting Officer Representative (COR). If the COR recommends additional requests based on programmatic needs and availability of funds, the Contracting Officer will authorize additional number of requests and obligate the required funds.

5. Are the costs of complex data requests and/or SAF preparation/release separately reimbursed to the contractor (i.e., rather than included in the contract budget)? We ask this because the RFP specifically states that the contractor should keep track of these specific costs, suggesting that these costs have a special status.

Response: The Government wants offerors to track costs for accounting purposes and to better understand how responsive USRDS is to the renal community. Offerors should propose budgets to address the requirements of the SOW and guidance provided in the responses to questions. Additional funds would only be authorized by the CO upon COR approval of requests that exceed annual limits (See SOW and response to Question 3).

6. Statement of Work:
Task 8 - Preparation of Standard Analysis Files (SAFs):
For the detailed cost report that’s due on January 15th of each year, should it include costs to prepare the SAFs internally over and above the 80,000 labor hours?

Response: Proposed costs for these tasks should be considered part of the overall budget. The estimated 80,000 labor hours is to perform all tasks during the 60-month period of the awarded contract. The Offerors are expected to submit proposals to perform all the activities described in the Statement of Work, including the various data requests.

7. Statement of Work:
Task 10 – Support for Complex Data Release Requests
i. Does it include costs for programming for the complex/linkage data requests?

ii. Is this effort separate from the 80,000 labor hours also? So, should we be keeping the 80,000 labor hours to other core activities and then budget extra effort for Task 8 and Task 10?

Response: The Government’s labor hours estimate of 80,000 includes labor required for performing all activities in all tasks described in the SOW. Offerors should use this as guidance and propose their own estimates of labor hours and personnel.
8. Currently, the USRDS CC/NIDDK is required to have an Exhibit Booth at the annual ASN Kidney Week Conference. We do not see any mention in the Statement of Work that asks about requiring the CC to have a booth at ASN. Should we be able to include information in our proposal regarding a booth for ASN and in our Budget include materials for the booth?

Response: Offerors should propose an Exhibit Booth at the American Society of Nephrology (ASN) kidney Week Conference.

- Details about the Conference are provided at ASN’s website: https://www.asn-online.org/
- Exhibitor information including pricing for 2018 ASN Kidney Week Conference are available at http://expo.jspargo.com/exhibitor/asn2018prospectus.pdf
- Information regarding the exhibit area services for Booths are available at: https://ordering.ges.com/025601060

Offerors are required to conform to the requirements of the conference at ASN in proposing for standard size (10’ by 10’) Exhibit Booths. Offerors should budget for travel for 2 staff members to the Conference and also for handouts, displays and signage, shipping, electricity, trash removal, and related Exhibit Floor services.

9. RFP: Article C.2. Reporting Requirements; a. Technical Progress Reports; 3. Annual Technical Progress Report for Clinical Research Study Populations, pg. 8: “If the clinical study(s) involves US and non-US sites, the US sites and non-US sites should be reported on separate Cumulative Inclusion Enrollment Reports.”

Response: Task 12 – “Transition of Care Cohort Study” is a special Study under the requirements of the Statement of Work for this RFP. Offerors should recruit renal patients in the United States, in accordance with the USRDS mission. Non-US sites are not expected as part of the study.

10. RFP: Article C.2. Reporting Requirements; b. Other Reports/Deliverables; 2. Source Code and Object Code, pg. 8:

How quickly will source code and object code be transitioned to a new contractor? During the transition, will there be opportunities to conduct knowledge transfer sessions with the outgoing contractor to ensure seamless transition?

Response: The Government plans to give a 90-day extension for the incumbent USRDS CC Contractor in order to complete transition activities and facilitate the transfer of software and handover of operations of the USRDS to the new awardee. This transition will be waived if the incumbent Contractor wins the new award.

11. RFP: Article H.20. Access to National Institutes of Health (NIH) Electronic Mail, pg. 54:

Will the contractor be required to utilize NIH email, or may corporate email be utilized to conduct business?
Response: Corporate email would be acceptable.

12. Statement of Work; III. Technical Requirements; 4. Preparation of Analysis Plan for the ADR, pgs. 30-31:
“Each year’s analysis plan shall include responses to comments received from the government COR, the External Expert Panel, and others in the renal community.”
Are the most recent analysis plan and related comments available for preparation of this proposal?

Response: This is the first time a formal analysis plan in response to EEP comments will be required, so responses to the EEP in the past were informal and included in the text of the ADR chapters individually. This would require furnishing draft notes of all the chapters which would not be feasible.

13. Attachment 3: SOW, General: Will all public-facing documents (including website material) require clearance through CMS, NIDDK, or both?

Response: All public facing documents will require NIDDK clearance.

14. Attachment 3: SOW, pg. 25-27: Maintain and Update the USRDS Data Archives: Will the DUA be submitted as a researcher or contractor? The DUA application and approval will follow different routes depending on the designation.

Response: The USRDS CC awardee will need to obtain 2 sets of DUAs:
   i. As the Contractor supporting Tasks 1-11 and Task 13
   ii. As the Researcher performing Task 12.

15. Attachment 3: SOW, pg 25-27: Maintain and Update the USRDS Data Archives: Do non-CROWNWEB data from CMS and other sources consist of the entire population, or are they limited to the claims for the ESRD/CKD/AKI population?

Response: The information in the USRDS data archives are primarily about renal patients except for a small percentage of the entire population whose data is made available for comparative analysis in research studies.

16. Attachment 3: SOW, pg.29: Transition Activities: Is analytic code and documentation included in the transfer of database and software (source code and object code)?

Response: All USRDS software and documents will be transitioned to the new USRDS CC awardee.
17. Attachment 3: SOW, pg. 5-6: Preparation of the ADR: Is a draft ADR expected by June 15 of the Base Year?

Response: A Draft ADR is due by June 15 of the Base Year. See also response to Question 18.

18. Attachment 3: SOW, pg. 5-6: Preparation of the ADR: Will the work completed by the incumbent contractor on the 2019 ADR be included in the transition to the new contractor?

Response: During transition, all the work done by the incumbent USRDS CC Contractor will be handed over so that a potential new USRDS CC Contractor can build on that to complete the ADR by the June 15th deadline.

19. Attachment 3: SOW, pg. 5-6: Preparation of the ADR: Are data collection activities included in this SOW, such as collecting information for the International Comparisons chapters?

Response: Yes, data collection activities are included in the SOW.

20. Attachment 3: SOW, pg. 34: Support for Standard Analysis Files Data Release: Does the task include evaluating investigator requests for SAF release and providing recommendations to the COR?

Response: Yes.

21. Attachment 3: SOW, pg. 34: Support for Complex Data Release Requests: Does the USRDS have standard/established linkage methodology?

Response: each contractor establishes the best methodology for the circumstances in conformance with accepted privacy policies and regulations, subject to NIDDK approval.

22. Attachment 3: SOW, pg. 33: Data Requests: For government data requests, is it only the COR that can request, or can other government agencies request data and have the COR’s approval?

Response: Other government agencies can request with NIDDK’s USRDS COR approval.

23. Attachment 3: SOW, pg. 35: .Org to .Gov Move: Could the new cloud site be used to house and fill data requests?
Response: Based on the large size of the data files that the current contractor is hosting, we would prefer a hybrid approach. NIDDK’s cloud would host the website and website-related data files. The authoritative data files could be stored in NIDDK’s on premise data center and managed by the contractor.

24. Are we permitted to submit a "Multiple PI" (MPI) application, and if so, how many MPI's would be considered acceptable? (i.e., are 5 or more MPI's acceptable?). If MPI is not possible, can we have site-deputy directors from each site?

Response: Offerors should propose only one PI in accordance with the evaluation criteria stated in Section M of this RFP.

25. Can the proposal have 5 to 10 subcontracts? Are there any limits on the number of permitted subcontracts?

Response: It is left to the discretion of the Offeror to propose subcontractors as it relates to the requirements in the statement of work. Refer to FAR 52.215-23 Limitations on Pass-Through Charges incorporated in the solicitation under Article I.2. Authorized Substitution of Clauses.

26. What is the recommended range/limit for direct budget costs? For example, is a direct range of $1M to 1.5M as the total DIRECT budget (excluding overhead or F&A) per year considered acceptable?

Response: The Government cannot provide such specific guidance. It is left to the discretion of the Offeror to propose direct budget costs as it relates to the requirements in the statement of work.

27. We would like to confirm if the RFA due date is 9/25/18, and if there is any possibility of extending the deadline for submission beyond this date.

Response: Amendment No. 2 to the RFP extended the deadline for the receipt of proposals to October 1, 2018.
Amendment No. 3 extends the deadline for the receipt of proposals further to 12:00 p.m. ET, Monday, October 8, 2018.

28. In terms of the technical evaluation factors, we would like to inquire if there is a recommended percent effort for our PhD biostatistician(s) and PhD epidemiologist(s).
Response: The Government cannot provide such specific guidance. It is left to the discretion of the Offeror to propose personnel and corresponding level of effort as it relates to the requirements in the statement of work.

29. We would like to clarify if subcontracts should complete the entire budget template, or only the categorical breakdown that is in the "Summary" and "Subcontracts" tabs (excel budget template below).

Response: Offerors must provide budget details for subcontractors using the same spreadsheet template used by the Prime contractor. In addition, subcontractors must also submit a justification to support each component of the proposed budget.

30. We would like to ask for clarification on the period of performance that should be included in the budget (please see below).
ARTICLE F.1. PERIOD OF PERFORMANCE

a. The period of performance of the contract awarded from this RFP shall be from February 8, 2019 through November 7, 2019.

b. If the Government exercises its option(s) pursuant to the OPTION PROVISION Article in Section H of this contract, the period of performance will be increased as listed below:

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<th>Option</th>
<th>Option Period</th>
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<tr>
<td>Option 1</td>
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</tr>
<tr>
<td>Option 2</td>
<td>November 8, 2020 - November 7, 2021</td>
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<td>Option 5</td>
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Response: Offerors must submit the budget on the template provided by NICHD for a total of 60 months. Budgets should be submitted separately for the 9-month Base period, each of the four 12-month option periods and a final three-month option period.

31. Does the main center (hub) need to have at least 51% of the budget, or does the main (hub) center need to have higher budget proportion that other centers, in case of a multi-center (sub-contract) approach?

Response: It is left to the discretion of the Offeror to propose Prime and subcontractor budgets as it relates to the requirements in the statement of work. Refer to FAR 52.215-23 Limitations on Pass-Through Charges incorporated in the solicitation under Article I.2. Authorized Substitution of Clauses.

32. Are there limited number of Deputy Directors? The current CC has 2 co-deputy directors, can there be 3 or more?

Response: Offerors should propose only one Deputy Director, in accordance with the evaluation criteria stated in Section M of this RFP.

33. Does the 50-page technical section include cited references? Does the cited reference section count towards the 50-page limit or not?

Response: Cited references should be included in the appendix and will not count towards the 50-page limit for technical proposals.

34. Are we allowed to include any Appendices with the proposal? Will they be counted towards the page limit? Will they be reviewed?

Response: While the appendix to the technical proposal does not count towards the 50-page limit, it should contain only the documents listed under SECTION J – TECHNICAL
PROPOSAL ATTACHMENTS, CVs/biosketches/resumes (no more than five pages) and cited references.

35. If Appendices are allowed, can we include Letters of Support in there?

Response: business proposals will require letters of commitment from subcontractors and consultants. These will not be evaluated by the Scientific Review Group.

36. Do References count towards the total page number up to 50?

Response: See response to Question 33.

37. Is it ok to propose 1 PI and 2 Co-Deputy Directors, as is the current paradigm?

Response: In accordance with the technical evaluation factors stated on the RFP, it is recommended that only one Director and one Deputy Director be proposed.

38. RFP, Attachment 1 & RFP, p. 132 - CV's are excluded from the page count. Does this include CV's for External Expert Panel (EEP) members?

Response: Resumes/CVs/biosketches are excluded from the technical proposal page count. Resumes/CV’s shall be included in the appendix and shall not exceed five pages.

39. RFP, Attachment 1 & RFP, p. 132 - Are letters of commitment from the EEP members excluded from the page count?

Response: They should be included in the business proposal which does not have a page limit.

40. RFP, p. 132 – Would NIH please differentiate between the experts for the EEP and the subject matter experts for the EEP? These are listed separately in the evaluation section of the RFP.

Response: That confusion is due to a typographical error. In Section M of the RFP on page 132, under the Technical Evaluation Criteria table, Personnel, (d) the sentence “Resumes and Letters of commitment of the experts proposed External Expert Panel” is hereby deleted.

41. RFP, Attachments - The links for attachments 8, 9, 12, 13, 19, and 20 do not work. The link for Attachment 23 leads to a blank Excel document. Would NIH kindly supply the missing attachments?

Response: For Attachment 13, Budget – click on the link “Electronic Contract Business Proposal”. Same template to be used by subcontractors.
The links for attachments 8, 9, 12, 13, and 19 do work and have been verified. Please email the Contracting Officer to receive these attachments via email if you are still unable to access these documents.

For attachment 20 -the corrected link is https://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/humansubjectstudy-v1.0.pdf

Attachment 23 – “Roster of Employees Requiring Suitability Investigations” is a Microsoft Excel spreadsheet that needs to be filled in by the new USRDS CC contractor after award. This is a form to be filled in by the Contractor for approval by the NIDDK COR and ISSO – and is not a blank document.

42. RFP, p. 77 – In “Separation of Technical and Business Proposals” on page 77, the RFP states, “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. The technical proposal must include direct cost and resources information, such as labor-hours and categories and applicable rates, materials, subcontracts, travel, etc., and associated costs so that the offeror's understanding of the project may be evaluated (See SECTION J, Attachment entitled, TECHNICAL PROPOSAL COST SUMMARY.) However, the technical proposal should not include pricing data relating to individual salary information, indirect cost rates or amounts, fee amounts (if any), and total costs....”

The first two sentences seem to contradict each other. Does NIH intend that offerors include the cost in the technical proposal?

Response: As stated on SECTION J, Attachment entitled, TECHNICAL PROPOSAL COST SUMMARY of the RFP:
Include Direct labor hours and total direct cost.
Do not include individual salary information, indirect cost or fee and total amount of the proposal. This information will be reviewed by the technical evaluators to assess offerors’ understanding of project and resource allocations.

43. RFP, p 77 -- Is Attachment 7, Technical Proposal Cost Information, excluded from the page count?

Response: It is one of the allowed appendices that must be completed and submitted with the technical proposal and is excluded from the page count.

44. General - Are references (i.e., bibliography) included within the 50-page limit for the Technical Application?

Response: See response to question 33.
45. a) **General** – Are letters of support included within the 50-page limit for the Technical Application?

*Response: See response to question 35.*

b) **General** – May offerors include an appendix to incorporate items that do not count toward the 50-page limit, i.e., CV’s, forms, etc.?

*Response: See response to Question 34.*

46. Page 157 of the RFP indicates "All USRDS data that have been acquired from Government sources, and from commercial vendors will be provided to the new USRDS CC Contractor for example, CMS, CDC, NHANES, VA, Optum, etc."

a) Will the NIDDK be providing data from the abovementioned commercial vendors through existing licenses/contracts (e.g., Optum), or is it the expectation of the USRDS CC Contractor to procure these data sources/contracts for the USRDS?

*Response: The Government will provide all required data.*

b) Is it permitted for the USRDS CC Contractor to have complementary experts from the abovementioned commercial vendors on their study team?

*Response: Only employees of the offeror and their subcontractors should be on the Study Team. No complementary experts should be included from any organization.*

47. Is it acceptable to have the position of Principal Investigator or Coordinating Center Director to be shared between two highly qualified individuals whose experience spans the SOW requirements for this position?

*Response – In accordance with the technical evaluation factors stated on the RFP, it is recommended that only one Director is proposed. Offerors may propose the 2nd individual as Deputy Director whose expertise complements that of the proposed CC Director.*

48. Should an offeror’s budget include funds for acquiring/purchasing data from the Centers for Medicare and Medicaid Services (CMS) to obtain Medicare claims and enrollment data, prescription drug event and plan data, assessment data (MDS, OASIS), Medicaid claims and enrollment data, CROWNWeb data, REMIS data, and UNODS data? If yes, please provide guidance regarding which files should be purchased and for which years?

*Response - No. The Government will furnish the necessary data for the USRDS CC.*
49. Should an offeror plan to acquire their own DUA directly from CMS to use CMS data, or are there other provisions for obtaining necessary DUAs? Are there DUAs from other agencies that must be acquired as part of this project?

Response – After contract award, the USRDS CC Contractor must obtain DUAs with each data source – CMS, Optum, VA, Kaiser, etc., indicating work is to be done on behalf of NIDDK.

50. Should an offeror’s budget include funds for assisting external users of data from Coordinating Center to acquire individual DUAs directly from CMS, or is there an internal DUA process solely managed by NIDDK?

Response – CMS is not involved in the DUAs with external investigators. All DUAs are done between external users and the USRDS CC after approval by the COR.

51. Should offerors’ budgets account for any costs associated with cloud storage and services for the USRDS website hosted on the .org domain or the .gov domain?

Response – The additional costs associated with the cloud hosting portion would be minimal and could be absorbed by the current NIDDK cloud service provider contract once the USRDS site is migrated to the .gov domain. There would be no charges for hosting the data files on NIDDK’s premise. All costs associated with hosting the .org domain would be the responsibility of the contractor.

52. RFP, SOW, page 27– Does NIH have an MOU or other agreement with CMS for USRDS use of CMS analytic resources, e.g., QualityNet workbench?

Response: For the USRDS project, NIDDK has an MOU for the sharing of CMS data. The NIDDK PO is not aware of MOUs or other agreements between NIH and CMS for the use of CMS analytic resources.