Section 4.1 LIMITATIONS ON LENGTH OF PROPOSAL is hereby amended to read:

The Technical Proposal for SBIR Phase II shall not exceed a total of 150 single-spaced pages, including all enclosures and attachments. The Business Proposal does not have a page limit. Pages should be of standard size (8.5" x 11") with a font size of 11 points (or larger). Excluded from the page limitation are cover letters and letters from collaborators and consultants, and your Phase I Final Report.

The following questions have been submitted to the NCI OA SBIR email address. The answers to these questions are provided below. The deadline to submit questions was Monday, February 24, 2014. Questions posted after the deadline were not addressed. Questions that were addressed in Amendments 1 and 2 are not listed below.

1. **Question**: In Section 4.3 (b), it appears that letters of commitment are to be provided by all key personnel, and by consultants. Is this correct? For Section 4.3 (e), we are securing strategic letters of commitment.

   Answer: Per Section 4.3(b) of the Solicitation: "Personnel - List by name, title, department and organization, the extent of commitment to this Phase II effort, and detail each person's qualifications and role in the project. <u>Provide resumes for all key staff members</u>, describing directly related education, experience, and relevant publications. Describe in detail any involvement of subcontractors or consultants, and provide resumes for all key subcontractor staff. <u>Also, include letters of commitment with proposed consultants confirming the extent of involvement and hourly/daily rate</u>. For FY 2014, the Consolidated Appropriations Act, 2012 (Public Law 112-74) signed into law on December 23, 2011, restricts the amount of direct salary to Executive Level II of the Federal Executive Pay scale. The Executive Level II salary is $179,700 (or $86.39/hour). Salaries for all personnel shall adhere to the current salary rate limitation.

2. **Question**: We are preparing our proposal for 307 "Novel Imaging Agents to Expand the Clinical Toolkit for Cancer Diagnosis, Staging, and Treatment." As a part of this proposal, we plan to include a clinical trial in patients with cancer. For the proposal budget, we try to determine if costs of clinical grade material that will be administered to patients during the trial could be included. The material was produced by the company in 2013 and is intended to be used for multiple clinical trials.

   Answer: Yes, this is an appropriate type of cost.

3. **Question**: Are there any other addresses available for delivery of the contract proposal?
   Example: 1)courier to hand deliver on Monday
   2)Overnight or Saturday delivery – FedEx

   Answer: Please comply with the delivery instructions as set forth in Section 8.1 of the Solicitation.

4. **Question**: Regarding the phase 2 NCI-SBIR contract proposal format: Can the CV's of key personnel be a pdf format attached to the document?

   Answer: Submissions must be in compliance with Section 7.2 of the Solicitation. Please see Section 7.2. of the Solicitation.

5. **Question**: Could we get clarification on the phase NCI-SBIR contract proposal for topic 277? Should the actual final report from the phase 1 contract be included in the submission? Should it be part of the research plan? Or submitted as a separate document?

   Answer: Please refer to Section 4.1 and Section 4.3 of the Solicitation.

6. **Question**: In the previously attached amendment, the link for Appendix A, Proposal Cover Sheet http://grants.nih.gov/grants/funding/sbircontract/contractappendixa.pdf, links to the Phase I proposal cover sheet. Will this be the correct form to use for the Phase II application?

   Answer: Please use this coversheet for your Phase II proposal.

7. **Question:** We had a foot of snow here and everyone is working from home so I wasn't sure if the government closed down today from the storm and I apologize for requesting again but I want to make sure you received my request for an extension on submitting our Phase II SBIR proposal. I need to take care of arrangements very soon.

   Answer: Unfortunately, we are not able to grant any extensions.

8. **Question**: In a phase II contract is there a certain percentage of the work (or money used) at the PIs facility. i.e. we need to have some non-human primate toxicology performed and this will be a major expense, and due to the GLP requirement has to be performed elsewhere.

   Answer: In accordance with Section 6.6 of the Solicitation, for Phase II awards, The National Defense Authorization Act for FY 2013 (January 2013) prohibits the prime from expending on subcontractors more than 50 percent of the amount paid under a contract. However, the Act excludes from the 50% limitation on any subcontracts with any "similarly situated entities" that have the same small business concern status as the prime contractor. For example, if the business concern is an 8(a) entity, it could subcontract work to other 8(a) entities without that work counting toward the limitation. Other "similarly situated entities" include small business concerns, women-owned small business concerns, women-owned small disadvantaged business concerns, service-disabled veteran-owned small business concerns, and HUBZone small business concerns. The Contracting Officer must approve deviations from these requirements in writing after consultation with the agency SBIR Program Manager/Coordinator.

9. **Question:** What is meant by "cannot be linked to a living individual"? Does this mean as long as they are anonymous to us, they are excluded? Or does this mean the patient must be deceased?

   Answer: If any of your investigators (company or UCLA or other subcontract) can link the data to patients, then this has to be called human subjects research. I refer you to the decision charts and human subjects instructions below (2 URLs) to help you decide how to handle your human specimen research in your proposal. But, based on your description, since the human subjects are living and it seems your subcontract investigators may have access to identifying information, it sounds like this qualifies as human subjects research and you would need an IRB approval in place by the time you begin the research involving the human specimens. However, depending on the investigators accces to identifying information, you may be able to claim one of the 6 human subjects research exemptions and thereby avoid the need for an IRB approval .

   http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html#c1

   http://grants.nih.gov/grants/funding/424/SupplementalInstructions.pdf#Part_II

10. **Question:** Does the situation, described above in Q9, fall under "research involving human subjects" and therefore we must fill out the documentation per "Human Subjects Research Guidance" (pg 36-57) or is it exempt? We will never interact with any of the human subjects, as that is currently done under the UCLA IND (which I can include in the application).

    Answer: It is hard for us to make this call for you based on the limited information you have provided. If your subcontract investigators have access to the identifying information, this qualifies as human subjects research. If UCLA already has an accepted IND and an active IRB approval covering this research, then all you will need is for your company to establish a human subjects assurance with OHRP, which you can do much later if your contract proposal is to be funded. I recommend you study the links above, and then if you want to send us a follow up e-mail proposing to categorize this human specimen research in a specific way , we can react to it. If there is no time for this, I recommend playing it conservative and calling this human subjects research. If the peer reviewers or NCI staff have concerns, they can be addressed after you submit your contract proposal.

11. **Question**: Additionally, we would like to utilize the UCLA-collected data from the PET scan (with no patient identifying material) to correlate with the biochemical assays from the human samples. We are not conducting the scans, merely receiving the data from the scans from UCLA. Is this exempt from the Human Subjects documentation?

    Answer: It is hard for us to make this call for you based on the limited information you have provided. See the second half of response under Q10 above. Study the detailed links provided and go from there.

12. **Question**: Page 23 of the solicitation states that "c. Three (3) competitive quotes." under Proposed Cost Breakdown requirements. Is this for equipment only or for *every* item in excess of $1K?

    Answer: Yes, you must provide 3 competitive quotes for all supplies/equipment exceeding $1,000. In accordance with the RFP, if equipment is available from only a single source please provide a justification along with the quote. Please provide a justification as to why the purchase of such equipment is allocable to the proposed research. Please provide a justification as to why the purchase of such equipment is allocable to the proposed research, as opposed to leasing or renting the equipment.

13. **Question:** We want to make sure we do not leave anything out and plan our project objectives accordingly; is performing an animal study a requirement for technical work proposed in Phase II for Topic 301?

    Answer: This topic is focused on in vivo applications of nano-sensing products to provide a readout on the tumor microenvironment. In Phase II, you must include an in vivo study in an animal model of cancer, as a prelude to a future in vivo study in human subjects, to be conducted after Phase II.

14. **Question:** We would like to work with a company to develop technology that is based in Canada, is this permissible?

    Answer: For both Phase I and Phase II, the R/R&D work must be performed in the United States. However, based on a rare and unique circumstance, a particular portion of the R/R&D work to be performed or obtained in a country outside of the United States may be approved, for example, if a supply or material or other item or project requirement is not available in the United States. Please also refer to *Performance Site Criteria under* Section 1.3 of the solicitation.

15. **Question:** We would like to propose a Principal Investigator for Phase II that did not work on Phase I, is this acceptable?

    Answer: Yes, proposing a new Principal Investigator for Phase II is permissible.

16. **Question**: We noticed that in the solicitation of Phase II Contract Proposals there is a page missing between page 87 and 88. At the bottom of page 87 and 88, it shows page 61 and 63 respectively. We would like to know if there is a page missing there. In addition, starting from page 87, pages from two sections SBIR Funding Agreement Certification and SBIR Funding Agreement Certification - Life Cycle Certification are blurry. Can you please provide us a clear version/pdf for both sections?

    Answer: There are no missing pages. The page number discrepancy appears to be a typographical error.

17. **Question**: During SBIR phase 1 we set up a sister company to handle the commercialization (selling & partnering & commercial manufacturing) of the product. For this phase 2, we would like to treat that sister company as part of String Therapeutics and not as contractor. Is that feasible?

    Answer: Any individuals directly employed with your company/organization specifically should be reflected in direct labor. All other labor associated with outside companies/organizations/individuals should be reflected as consultants or subcontractors as applicable/appropriate.

18. **Question**: We could not find an example of a successful Phase II proposal to NCI on the website, but would appreciate a model of what a successful one looks like. We would also appreciate clarification as to the NCI's expectation for our Phase II outcomes ie. For us it will be entering phase 1 clinical trial.

    Answer: We do not post examples of successful proposals.

19. **Question:** For the submitted paper-version of the proposal, should a print out of all the tabs be included, or do you only require the summary tab and a separate budget justification sheet?

    Answer: All tabs must be included, even if there are tabs which may not have any costs reflected therein.

20. **Question:** I have downloaded what I believe to be the right cost spreadsheet, can you please confirm that this is correct for our Phase II contract RFP?

    Answer: Please utilize the following link: Breakdown of Proposed Estimated Costs (plus fee) w/Excel Spreadsheet.

21. **Question:** Budget. On the issue of Contract budget maximum, will consideration be given to the $1.5M cap should the forecasted expenses exceed the cap due to the costs of the evaluation in small animal models and extended testing of such Small Animal Imaging activities including the use of varied magnetic strength MR scanners, and additional staff requirements?

    Answer: In accordance with the Solicitation, it is strongly suggested that proposals adhere to the designated budget amounts and project periods. As a reminder, proposals with budgets exceeding the above amounts and project periods may not be funded.

22. **Question:** " We are in the process of completing our Phase II application and wanted to know if we are allowed to **submit ONLY the Summary of Proposed Costs worksheet** and NOT the additional Back up pages.

    Answer: You must provide a complete version of the following document with your submission: http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/buscost.htm.

23. **Question:** We are planning to submit a multi-PI SBIR PhaseII contract, where the contact PI is from the Company which was awarded a Phase-I contract. We plan to have another PI from the non-profit institute, which was the sub-awardee in the Phase I. Is this allowed and are we OK to go ahead.

    Answer: Please refer to Section 1.3 of the Solicitation that provides guidance on Multiple PIs. Please note that it states: "For Multiple PD/PI proposals: The first PI listed must be affiliated with the small business concern organization submitting the proposal and will serve as the Contact PD/PI. The primary employment of the "Contact PD/PI" must be with the small business concern at the time of award and during the conduct of the proposed project."

24. **Question:** Do you have any thoughts on when we may be able to start the Phase II SBIR contract, if awarded. Our subcontractor needs the period of performance to get documents routed internally.

    Answer: Dates have not been determined at this time.

25. **Question:** For budget planning purposes, can you please tell me the earliest the Phase II contract could start after it is submitted?

    Answer: Work may begin on the effective date of the contract.

26. **Question:** Also can work on the contract start before an award letter is given? The reason I ask is that for NIH grants, awardees can retroactively bill towards a grant 60 or 90 days before the award date.

    Answer: No, work may begin on the effective date of the contract.

27. **Question:** I will be hand delivering my copies of the Contract Proposal – and want to get a date stamp that they have been received, do I come to the reception and ask for you?

    Answer: If delivering the proposal in person, please utilize the name and address identified in Section 8.1. You will be asked at the security station for a point of contact and/or phone number. Please provide: 240-276-5440 and my name Victoria Cunningham.

28. **Question:** In Section 4.3 (b), it appears that letters of commitment are to be provided by all key personnel, and by consultants. Is this correct? For Section 4.3 (e), we are securing strategic letters of commitment.

Answer: Per Section 4.3(b) of the Solicitation: "Personnel - List by name, title, department and organization, the extent of commitment to this Phase II effort, and detail each person's qualifications and role in the project. <u>Provide resumes for all key staff members</u>, describing directly related education, experience, and relevant publications. Describe in detail any involvement of subcontractors or consultants, and provide resumes for all key subcontractor staff. <u>Also, include letters of commitment with proposed consultants confirming the extent of involvement and hourly/daily rate</u>. For FY 2014, the Consolidated Appropriations Act, 2012 (Public Law 112-74) signed into law on December 23, 2011, restricts the amount of direct salary to Executive Level II of the Federal Executive Pay scale. The Executive Level II salary is $179,700 (or $86.39/hour). Salaries for all personnel shall adhere to the current salary rate limitation.

29. **Question:** Do you have a document where the links are active, as opposed to an image of the signed amendment?

    Answer: A copy of active links is not available. Please utilize the links identified in the Amendment.

30. **Question:** I am in the process of writing the main part of the proposal and came up with a question. I am more used to the NIH SBIR grants vs. contracts. On providing the details of the Phase II personnel, the RFP states to include the resumes of the key staff members. Could I list the personnel and summarize their background in the research plan and add the NIH biosketches of the key invdividuals in the appendix? It seems this would be easier to read (and I would refer to the appendix with page number for each person).

    Answer: In terms of the location, please ensure key staff member resume information is contained in the technical proposal and the technical proposal meets the page limitations identified in the solicitation.

31. **Question**: For the Phase II Proposal, there does not appear to be a limit to the number of letters/spaces allowed for the Project Title. We intend to keep it close to the length of our project title for the Phase I (49 letters/spaces), but may go to a total of 60. Is this acceptable?

    Answer: Per the Sample Statement of Work, "TITLE: (Normally carries the same title as Phase I, but may be changed if the previous title no longer accurately describes the project.)". A particular character limit has not been identified in the Solicitation.

32. **Question:** I am unsure of the requirement for Appendix F, Summary of Related Activities and the differences between the listed items a-c, specifically b and c. Are you able to provide additional instructions on this requirement? Requirement "a", seems to be asking for ongoing awards. Correct?

Under “a” and “b”, “Total Effort Committed” – are you looking for a % of Effort?

Requirement “b” seem to be asking for pending awards. Correct?

Is requirement “c” additional explanation of requirement “b”?

What specifically are you looking for under “Total Proposed Effort.” Is this a narrative description of their role on the project?

Answer: “A” addresses your current effort expended on existing contracts/projects. Under “A” and “B”, “Total Effort Committed” please list total percentage of effort. “B” represents your total percent of effort potentially expended on pending contracts/projects. “C” is the level of effort expended on this proposal. No “Total Proposed Effort” is not a narrative. It is just a percentage of the proposed individual’s time commitment.

33. Question: We have 2 - 3 laboratories set up as collaborators, who would each have the instrumentation for a period of ~3 - 6 months. This would allow them to generate a strong set of data that fulfill the above requirements. Would positioning the equipment based on reasonable assumptions of prototype cost and the amount of time necessary to generate an appropriate dataset for evaluation be sufficient?

Answer: Yes, as long as you can verify the statistical significance with the proper power calculations to determine the sufficient number of patient samples which will give the appropriate consideration of statistical significance.

34. Question: Can I exceed the funded amount limitation set forth in the solicitation?

Answer: Offerors are encouraged not to exceed stated funding limitation.

-END OF AMENDMENT-