AMENDMENT OF BROAD AGENCY ANNOUNCEMENT (BAA)

BAA Number N44CM47014-11
Amendment Number: 3

AMENDMENT THREE (3)

Issued by:

National Cancer Institute
National Institutes of Health
9609 Medical Center Drive
Building 9609, Room 1E558
Rockville, MD 20850

Broad Agency Announcement Number:

N44CM47014-11

Date of Broad Agency Announcement Issuance:

December 18, 2014

Date of Amendment No. 1 Issuance:

December 30, 2014

Date of Amendment No. 2 Issuance:

January 13, 2015

Date of Amendment No. 3 Issuance:

January 21, 2015

Number of Pages:

5 Pages

NCI Point of Contact:

Rosemary Hamill, Contracting Officer
E-Mail: ncioasbir@mail.nih.gov

The hour and date specified for receipt of Offers remain unchanged, 3:00 PM Eastern Standard Time on February 3, 2015.

Offerors MUST acknowledge receipt of the amendment by Amendment number(s) and date of the amendment on the NIH Form 2043 (Attachment 13).

FAILURE OF YOUR ACKNOWLDEGEMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER.

Except as provided herein, all terms and conditions of the Broad Agency Announcement remain unchanged and in full force and effect.

PURPOSE OF BROAD AGENCY ANNOUNCEMENT AMENDMENT #3

The purpose of this amendment is to provide additional Questions and Answers related to this solicitation.

The following questions were received and the responses are below:

Question**:** Are we restricted to resubmitting our original Phase II proposal with modifications? If so:

a. We would have no more submission opportunities for this proposal, correct?

b. How much can we change in the Specific Objectives and Tasks?

c. Will the reviewers have access to our prior Phase I application and final report?

Response: You can submit a completely new Phase II that is based on the outcome of Phase I and that addresses published Phase II deliverables.

Reviewers will have access to the Phase I final report to the extent that it is provided in the Phase II technical proposal. Note: Technical Proposal Instruction 3.6.1.4, (p. 19 in the BAA), "Achieved Result of Phase I Effort" provides the instruction that "In addition to including a copy of the Offeror's SBIR Phase I Final Report, briefly discuss and summarize the results of the Offeror's Phase I effort so that the reviewers can assess the achievements of the Offeror's Phase I contract."

Question: Can we submit a completely new tumor microenvironment Phase II proposal? If so:

a. Would this count as a first submission and would we be able to resubmit later?

b. If it is a first submission, can we resubmit to another (non-contract) SBIR opportunity?

c. A new Phase II proposal will require significant background and justification. Is there a page limit on the Research Strategy section?

d. If we include animal studies we must identify where the animals will be housed but not IUCAC protocols, etc…, however, that material must be supplied before work commences, correct?

Response: For contract proposals, we don't count submissions as is done with grants.

Page limitations are included in Section 3.2 of the solicitation (Page 17).

You can submit in February, and if that one is unsuccessful, you may or may not be able to submit a Phase II contract proposal again next year (approx. Feb 2016) depending on whether the topic is solicited again next year. However, you could definitely submit again as a grant, as long as the proposal is not identical to the contract proposal. There are 3 grant deadlines every year.

Statement d is correct as written.

Question: Would it be acceptable to use a China-based Contract Manufacturing Organization for the synthesis?

Response: No.

Question: Would it be acceptable to purchase the starting material according to the Buy American Act?

Response: Yes. You can purchase raw materials from a foreign source using SBIR funds but said funds cannot support work done in a foreign country. SBIR policy says work has to be done in the US, but it does not restrict sources for purchase of raw materials.

Question: Can part-time employees be included in the Offeror's labor pool?

Response: Yes.

Question: "The short-term goal of the project is to perform proof-of-principle technical feasibility demonstration of innovative radiation source or source components. The long-term goal of the project is to develop a robust, reliable radiation source and to incorporate it into a radiotherapy system."

How is long-term defined? 24 months? 10 years? Does this mean that whatever the Offeror proposes must show clinical operation modes within the 24 months of the Phase II contract?

Response: The long term goal is beyond the scope of the Phase II project. We do not expect clinical operation within the Phase II.

Question: Is Phase II proposal expected to be an extension of Phase I, focusing on the same type of compounds?

Response: Yes, Phase II is meant to build on the results in Phase I.

Question: How many Phase II projects will be funded for Topic 321?

Response: This has not yet been decided but will depend on the outcome of peer review, programmatic balance, and available funds.

Question: Our proposal is for a Phase II. Should we use this form (Appendix A Cover Sheet) or is there one that we can substitute to eliminate any confusion?

Response: We opted to use the Phase I form (for this Phase II solicitation) because it provides more helpful information to us than the one intended for Phase II proposals.

Question: Regarding Topic 321 of this BAA. Under Activities and Expected Deliveries it is mentioned to: "Expand the reducing glycan libraries representative of a sector(s) of the mammalian glycome and not presently commercially available to at least 100 compounds". Since we have produced and delivered 24 compounds under the prior SBIR Phase I contract, it is our assumption that we have to produce and deliver 76 additional compounds under Phase II of the current BAA. Could you confirm that our assumption is correct?

Response: Correct. You would need to produce 76 additional compounds that are not presently commercially available."

Question: Does the contract allow a small business concern to use a NCI research staff as a subcontractor?

Response: No. However, NCI research staff can be unpaid collaborators. You can submit letters in the proposal stating their role and time commitment for the project but they should be unpaid collaborators.

Question: According to Amendment 1, in the business proposal you provide an excel spreadsheet (noted as item #14 on page 18 of Amendment 1). In the original solicitation, section 3.7 (Business Proposal) has an item 3 within Section 3.7.4 (page 48). Can you explain if a completed Entire Workbook (all sheets) noted as item #14 needs to be submitted as part of the proposal package? Do we submit printouts of each sheet within the entire workbook as part of the Business Proposal? Do we also need to provide a completed workbook for each subcontract?

Response: Item 3 in Section 3.7.4 (page 48) references the excel spreadsheet whose updated link was provided in Amendment 1. It is expect that all relevant parts of this workbook will be completed and provided as part of the Business Proposal. This is for subcontractors as well.

Question: I'm unsure if we need a data and safety monitoring plan. We are using patient samples but with no direct information to the patient. We are just validating a prototype in this case.

Response: Sounds like you are using human samples, but not live human subjects. So you do not need a clinical data and safety monitoring plan. Such plans are only required for human clinical trials.

Question: What cost information is required from subcontractors for the phase II contract?

Response: We look for the same kind of cost breakdown from subcontractors as we do from prime contractors. We must have adequate information to determine that the costs are fair and reasonable. In particular, we need a breakdown for direct labor, material and supplies, other direct costs, etc. If equipment or travel is proposed, we need a strong justification and breakdown. We also need a copy of the subcontractor's indirect cost rate agreement.

Question: Page 13 of the BAA Amendment: "Topic 314 Development of Human Tissue Culture Systems that Mimic the Tumor Environment (Page 78) is revised to replace the link with the following: http://www.ncats.nih.gov/research/reengineering/tissue-chip/tissue-chip.html" This link takes me to the DARPA/NCATS Human on a Chip program, not the updated NCI 314 topic.

Response: The Amendment #1 included the intended link for that narrative: http://www.ncats.nih.gov/research/reengineering/tissue-chip/tissue-chip.html

If you need a link to NCI Topic 314, please try: http://sbir.cancer.gov/funding/contracts/fy2013_02.asp

Question: Can our Title for the Phase II Contract be different from our Phase I Contract Title?

Response: Yes, as long as it stays product focused.

NOTE: The Questions and Answers period closed on January 16, 2015.