AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID CODE	PAGE 1 OF 15

2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO. *(If applicable)*
0002	11/20/2013		

6. ISSUED BY CODE

National Cancer Institute
Office of Acquisitions
9609 Medical Center Drive, 1E564, MSC 9705
Bethesda, MD 20892-9705

7. ADMINISTERED BY *(If other than Item 6)* CODE

8. NAME AND ADDRESS OF CONTRACTOR *(No., street, county, State and ZIP Code)*

TO ALL POTENTIAL OFFERORS

CODE FACILITY CODE

(X) ☒ 9A. AMENDMENT OF SOLICITATION NO. PHS 2014-1

9B. DATED *(SEE ITEM 11)* 08/29/2013

☐ 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 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 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 your 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 1 copies to the issuing office.

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

The purpose of this amendment is to:

Extend the proposal due date to December 3, 2013 at 4:30PM Eastern Time, respond to Offerors questions, and provide the form entitled "SBIR Funding Agreement Certification" which is required to be executed at time of contract award, and clarify the number of proposals to be delivered. Accordingly, the solicitation is amended as follows:

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.

15A. NAME AND TITLE OF SIGNER *(Type or print)*		16A. NAME AND TITLE OF CONTRACTING OFFICER *(Type or print)*	
		Christopher Scott Contracting Officer	
15B. CONTRACTOR/OFFEROR *(Signature of person authorized to sign)*	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA *(Signature of Contracting Officer)*	16C. DATE SIGNED 11/20/2013

Accordingly, the closing date and the deadline for receipt of proposals is revised from November 25, 2013, 4:30PM Eastern Time to December 3, 2013, 4:30PM Eastern Time.

Please note that no further questions will be accepted.

The link to the SBIR Funding Certification Agreement is as follows:
http://grants.nih.gov/grants/funding/sbir_forms/SBIR%20Funding%20Agreement%20Certification.pdf

Section 8.9. Proposal Checklists, is revised to reflect the following changes:

Phase I Proposal:

Item 1:
a. Proposal Cover Sheet Appendix A (1 Original, 5 Copies)

b. Table of Contents

c. Abstract of the Research Plan, Appendix B (1 Original)

d. Content of the Technical Element

Item 2: Pricing Proposal (Appendix C) (1 Original, 5 copies)

Item 3: SBIR Application VCOC Certification
(See Section 4.5 to determine if this applies to your organization)

Item 4: Proof of Registration in the SBA Company Registry
(Refer to Section 4.16 for Directions)

Section 13- APPENDICES is revised to incorporate APPENDIX H – SBIR FUNDING AGREEMENT CERTIFICATION.

General Questions

Question 1: May I submit my proposal electronically?

Answer: The NIH and CDC do not currently accept electronic proposals. The original proposal, along with the required duplicate hard copies of the proposal, must be submitted at the address specified for the appropriate HHS Component or Topic indicated in Section 10 of the solicitation. See section 7.3 How To Submit Proposals.

Question 2: Who should I contact with questions on technical matters or contract administration?

Answer: Consult Section 10 of the solicitation for the Contracting Officer's contact information that is responsible for responding to questions concerning your topic of interest.

Question 3: I know the SBIR Program Manager (Contracting Officer's Representative) that is in charge of a specific topic. Why can't I call them directly with my questions?

Answer: Once the solicitation is released, all communications concerning the acquisition must be directed through the Contracting Officer who will facilitate technical discussions. Once contract awards are made contractors are free to interact with the Contracting Officer Representative.

Question 4: Can I submit the same project as a proposal for a contract and as a grant?

Answer: No, you may not submit both a contract proposal and a grant application for essentially the same project to the same or different awarding component(s) of the NIH/CDC. The only exception is after a contract proposal has been evaluated and is no longer being considered for award, you may submit a grant application. See Section 4.18 Prior, Current, or Pending Support of Similar Proposals or Awards in the solicitation.

Question 5: How do you I know you received my proposal?

Answer: There is no automatic acknowledgement of receipt of your proposal. It is strongly advised that you save tracking information from the mailing so that you can track the delivery of your proposal.

Question 6: How do I find out about the status of my proposal and the date my proposal will be reviewed?

Answer: We do not currently have a portal through which you can track your proposal through the award process. The NCI does not utilize eRA Commons for tracking contract proposals, so please be advised this information will not be available in eRA Commons as it is with grant applications. Please contact the Contracting Officer assigned to your topic in Section 10 of the solicitation for an update on your proposal.

Question 7: How will I know who else has submitted a proposal under my topic?

Answer: This acquisition is governed by the Federal Acquisition Regulation. Accordingly, offerors are not entitled to information concerning the names or proposal details of competitors. Information about organizations which have been awarded contracts can be

found on the NIH RePORTER site that contains information about grant and contract awards: http://projectreporter.nih.gov

Question 8: I didn't find out about the solicitation until recently and it will take time to put the proposal together. Can I submit my proposal late?

Answer: Please refer to Section 7.2 of the solicitation. In general "Late" proposals will not be accepted.

Question 9: I am doing research on X. Is there a topic on X? Do you fund X? Can we submit a proposal in response to this contract solicitation PHS-2014-1?

Answer : Before your inquiry can be addressed, you need to identify which technical topic you would be responding to under PHS-2014-1. We are only soliciting contract proposals under specific topics. Please review Section 12 of the solicitation COMPONENT INSTRUCTIONS AND TOPIC DESCRIPTIONS to determine if your project would fall within one of the topics outlined, and if you feel your project could fulfill the requirements specified.

Question 10: There is no topic in the current solicitation that is in my business's area. Should I wait for the next solicitation? What can I do?

Answer: There are a number of funding opportunities available through the NCI SBIR/STTR programs. If there is no contract topic being solicited, please check available grant funding opportunities here: http://sbir.cancer.gov/funding/receipt_dates.asp
In general, if you are working on a research project within the mission of the NCI, advancing cancer research, prevention, diagnosis, or treatment, then you may apply through the Omnibus solicitation, the NIH investigator-initiated funding opportunity. Learn more about the Omnibus here: http://sbir.cancer.gov/funding/omnibus/

Question 11: Can you recommend us for SBIR/STTR Phase 1 grant application submission?

Answer: In general we cannot recommend opportunities. Please review the NIH SBIR website. All current and open Requests for Grant Applications, as well as this Request for Contract Proposals can be found. You must read and review the descriptions of these opportunities to determine if they are of interest to your organization. Each opportunity lists a point of contact if you have specific questions.

Question 12: Why do I always have to reference my inquiry with a topic number?

Answer: We ask that you reference your topic number of interest so that we can quickly refer you to the correct agency.

Question 13: Are the slides available from the October 30 webinar hosted by the NCI?

Answer: Yes, here: http://sbir.cancer.gov/pdfs/2013-10-30_nci_sbir_contracts_webinar.pdf

Question 14: Can I propose a greater budget than is listed on the topic?

Answer: While you are allowed to propose a greater budget than is listed, this is a competitive process, and it is strongly advised that proposals adhere to the budget amounts and project periods. Proposals with budgets exceeding the specified amounts and project periods may not be funded. Section 12 of the solicitation has a description of each topic with a dollar value specified.

Question 15: Are all the milestones outlined in the topic description expected to be met, or would achieving one or two of them be sufficient?

Answer: It is generally expected that all the milestones would be met, though this may depend on the particular topic.

Question 16: Can funds be used to participate in training programs to evaluate your market potential?

Answer: SBIR funding is intended for use in research and development activities, and thus excludes use for market analysis or training. However, you may include a request for technical assistance funds of up to $5000. If you wish to request technical assistance funds, you are required to include these costs in your budget and provide a detailed budget justification. Refer to Section 8.1 for how to include this in your Pricing Proposal. Refer to Section 4.20 for a description of the eligible types of technical assistance services.

If the amount of $5000 is included in your cost proposal and is determined to be appropriate and allowable for technical assistance, this will be in addition to the amount negotiated per award, and as specified in the topic description.

Please note, if funds are requested to utilize your own technical assistance vendor and an award is made, the awardee is not eligible to apply for the NIH-provided technical assistance program for the phase of their award.

Question 17: I want to use a foreign subcontractor, may I?

Answer: No. Please refer to Section 4.2 Offeror Eligibility and Performance Requirements of the solicitation.

Question 18: How much preliminary data is required?

Answer: There is no requirement for preliminary data for Phase I proposals. However, competitive applications almost always include a substantial amount of preliminary data, as this is a competitive funding environment. Consider including preliminary data to establish a foundation for your project proposal to make it competitive.

Question 19: What is the proposal structure? What are the page limits and required sections?

Answer: See Sections 7 and 8 in the solicitation. SBIR Phase I technical proposals shall not exceed 50 pages. SBIR Phase II technical proposals shall not exceed 150 pages. Pages in excess of the page limitation will be removed from the proposal and will not be read, considered, or evaluated. Section 8 details proposal preparation and instruction, including all required sections.

Question 20: Can you send me a sample proposal? Sample budget pages?

Answer: We do not provide sample documents. For detailed instructions on how to fill out budget pages and definitions, please refer to the solicitation, section 8, http://grants.nih.gov/grants/funding/SBIRContract/PHS2014-1.pdf

Question 21: Specifically what do we need to do to respond to this solicitation?

Answer: You must read the solicitation and determine if your organization is eligible to compete, if your project would address the technical topic requirements, and follow the directions for submitting your proposal as detailed in sections 7 PROPOSAL SUBMISSION and 8 PROPOSAL PREPARATION AND INSTRUCTIONS of the solicitation.

Question 22: How do we describe commercial potential? What is the difference in the commercialization sections in contract proposals compared to grant applications?

Answer: It depends on the technology. For some technologies, such as drug development, it is appreciated that there will be large capital requirements and long time-frames for ultimate marketing and regulatory approval for a new therapeutic. In this scenario, commercial potential involves determining whether there is a reasonable plan in place to secure regulatory advice, a preclinical plan in place to achieve critical milestones and hit key inflection points to bring additional investors to fund the next stages of development. For research tools with no regulatory path, the plan may be more specific, including manufacturing, talking to key customers, specifying your competitive advantages with a comparison of competing technologies.

For Phase I contract proposals, review criteria includes an evaluation of the commercial potential and commercial applications, so more emphasis is placed on commercial potential in

the Phase I contract proposal than in a Phase I grant application. The commercialization sections would be similar for Phase II contract proposals and grant applications.

Question 23: May I submit a proposal for a Phase II only project under this solicitation?

Answer: No. Specific topic descriptions will indicate if a Fast Track proposal will be accepted. Fast Track is for NIH projects only and a proposal for Phase I and Phase II work must be submitted simultaneously when Fast Track proposals will be accepted.

Question 24: What are the pros and cons of a Fast Track submission compared to delaying a Phase II submission for a contract proposal? If a Fast Track contract is funded only for Phase I, what is the timeline for a Phase II proposal submission?

Answer: For a Fast Track contract proposal, the Phase I proposal and Phase II proposal are reviewed and scored independently, unlike with a grant Fast Track application, which is reviewed as a single application. One implication is that if the Phase I contract proposal scores well, but the Phase II proposal does not, the NCI may elect to consider only the Phase I proposal further for award.

The biggest consideration on whether to submit a Fast Track is how much preliminary data you have to suggest a relatively low level of technical risk for the Phase I portion of the study. Put yourself in the mind of a reviewer; if there's too much risk and too many questions based on the Phase I work, it would be difficult being comfortable going forward with the full project without getting the early Phase I data.

Question 25: May I submit a proposal for only Phase II work?

Answer: You may not submit a proposal for Phase II work only in response to the solicitation PHS2014-1. All successful Phase I offerors will be eligible to compete for a Phase II award, upon completion of the work under their Phase I contract award.

Question 26: Can a Phase I contract awardee apply for a Phase II grant?

Answer: Yes, a Phase I contract awardee can apply for a Phase II grant.

Question 27: Can a Phase I grant awardee apply for a Phase II contract?

Answer: No, you must be a successful recipient of a Phase I contract award and perform that effort in order to be eligible to compete for a Phase II contract.

Question 28: How many proposals do you expect to receive for each topic?

Answer: We do not know how many proposals we will receive for each topic, as it varies from topic to topic and from year to year. In the past, some topics have received 0 – 2 proposals, while others have received 15 – 20 proposals.

Question 29: What are the historic funding rates (percentage of proposals) for NCI SBIR contracts?

Answer: Identifying a historical percentage is not useful for contracts, because each topic differs from each other and changes from year to year. In section 12, each topic specifies an anticipated number of awards.

Question 30: Do reviewers of grants and contracts have similar backgrounds (e.g. academia vs. industry)?

Answer: Yes. In SBIR study sections and review panels, mix of reviewers with industry backgrounds and academic backgrounds. For contract topics, reviews are very focused, in finding reviewers well-suited for particular topics. Cover the science, as well as the business space.

Question 31: What is a promising score in the likelihood of being funded for a contract?

Answer: Contract proposals are scored from 0 – 1000, with 1000 being the best score. For a score to be considered competitive, it depends on the contract topic. Generally, 800-900 would likely be competitive. Sometimes a score of 600-700 could be competitive, sometimes not. In addition to the score of a particular proposal, whether a contract is selected for award depends on a number of factors, including: the distribution of scores, the amount of funding available for a particular topic, the distribution of types of technologies proposed in a particular round, and the interests and priorities of the NCI.

Question 32: Is the proposal due date extension for all topic areas?

Answer: Yes. The closing date and the deadline for receipt of all proposals under solicitation number PHS-2014-1 is December 3, 2013, 4:30PM Eastern Time.

Question 33: Our company is currently preparing a proposal in response to the PHS 2014-1 solicitation, topic 027, and I was wondering if you could clarify a question I have about proposal length. The solicitation specifies a 50 page limit for the 'Technical Proposal', does this limit also include the Appendix C Pricing Proposal and the SBA proof of registry? Or is this limit just for what is listed as the 'Technical Element: Item 1', and not the other Items?

Answer: Per solicitation PHS-2014-1, Section 7.1, Limitation on the Length of the Technical Proposal, SBIR Phase I technical proposals (Item 1) shall not exceed 50 pages. See Section 8,

Proposal Preparation and Instructions, of solicitation PHS-2014-1 regarding the components of Item 1.

Question 34: Is international use of the technology funded by SBIR grants a positive benefit to include in the proposal, or is this primarily focused on domestic (US) issues?

Answer: SBIR is domestically focused. Please see:
http://grants.nih.gov/grants/funding/sbir_faqs.htm#507

Question 35: What makes an SBIR VOI grant successful? Is it expected to have an academic VOI expert on the grant?

Answer: Technical Evaluation Criteria are identified in "6.2 Phase I Technical Evaluation Criteria", and include soundness and technical merit of the proposal, qualifications of the PD/PIs including expertise of those named in the proposal, innovation, commercialization potential, and facilities. The PD/PI is expected to bring together the appropriate team to ensure the necessary expertise is available for the proposed work.

Question 36: Have you had many inquiries about this project?

Answer: This is a competitive process and we cannot provide this information.

Question 37: Can you direct me to a list of sample review committee members on the Web?

Answer: These reviews are conducted by Ad Hoc committees and this information is not releasable.

Question 38: I noticed this solicitation is listed as a SBIR contract as opposed to a SBIR grant. Is there any significant different between the two that I should be aware of?

Answer: Yes there is a difference. A grant and a contract are two different mechanisms. Grants and Cooperative Agreements are financial assistance mechanisms. The principal purpose is to transfer funds, resources, technical assistance or expertise to a recipient to accomplish a public purpose authorized by federal law. They engage public health stakeholders, including state and local governments, in fulfilling CDC's mission. The primary beneficiary is the public.

A contract is an acquisition or procurement mechanism. The principal purpose is to acquire ("purchase, lease, or barter") property, goods or services for the direct benefit or use of the United States Government. The primary beneficiary is the federal government. In this instance, the particular topic you want to address is listed under the contracts portion of the SBIR program and the focus is for the benefit of the federal government.

Question 39: My question is in regards to the format. I see that the page guidelines list a maximum of 50 pages for phase 1 proposals and also gives an outline for the technical element. Are there any other further guidelines on suggested page limits for the various sections in the technical element (e.g. the Research plan is typically 6 pages or less according to the SF424 format guide) or is it just up to us to choose how to distribute the content among those 50 pages?

Answer: As outlined in 7.1 of the SBIR solicitation, SBIR Phase I technical proposals shall not exceed 50 pages. It will be up to the vendor on how they will distribute the content among the 50 pages. Again, there are no exclusions to the page limit-the technical proposal shall not exceed 50 pages for Phase I.

Specific Topic Questions:

Topic 004: Improved Rapid Antimicrobial Susceptibility Testing from Primary Specimens

Question 1: With respect to Project Goals b/c), is the assay required to identify the mechanism of resistance in addition to being able to reliably assign resistance to the specific pathogen causing the patients infection?

Answer: No, determining the specific mechanism of resistance is not a requirement. However, the methods/technology is required to demonstrate that any antimicrobial resistance mechanism detected, e. g, a beta-lactamase gene, is phenotypically expressed and functional, resulting in clinically relevant resistance that can inform treatment.

Question 2: What is the minimum number of pathogens to test to satisfy the project goals for Phase 1 proof-of-concept?

Answer: There is no minimum number, but the pathogens tested must include one agent of bioterrorism such as *Bacillus anthracis, Francisella tularensis, and Yersinia pestis, Burkholderia mallei and Burkholderia psuedomallei, Brucella* spp., and *Coxiella burnetii.* However, the CDC is particularly interested in methods/technologies that can detect phenotypic resistance or susceptibility in agents of bioterrorism, microorganisms routinely found in clinical specimens, and methods, technology, and equipment that are not pathogen specific but can assess antimicrobial susceptibility or resistance in a variety of pathogens.

Question 3: During method/technology development is there a preference for the assay to be evaluated using either antibiotic resistant or susceptible pathogens?

Answer: The assay should be evaluated using both resistant and susceptible strains of each pathogen.

Question 4: Can antibiotics within the same class be substituted for those listed in the solicitation (i.e., ciprofloxacin, doxycycline, penicillin, gentamicin, and ceftazidime)?

Answer: No, the assay must be able to determine antimicrobial resistance or susceptibility for one or more of the antibiotics listed in the solicitation.

Topic 10: Formulation of Nootkatone in Soaps and Lotions for Lyme Disease Prevention

Question 1: Will CDC supply to the applicant company the nootkatone produced from various sources, or is it up to the applicant company to procure these? (The topic description says "Sources of nootkatone will include plant derived extracts as well as novel yeast fermented product derived from natural precursor compounds that are less expensive than direct plant derived products.")

Answer: No, it is up to the company to procure these.

Question 2: To CDC's knowledge, are there any patents or other intellectual property restrictions that would preclude an applicant company from performing this work? If so, could you inform us as to what licenses or other agreements might be required?

Answer: CDC holds 3 patents (1 of which covers US, Canada, Australia, and Europe). We currently have a commercial evaluation licensing agreement with 2 companies. That licensing agreement runs thru Jan 15, 2014. However, this would not preclude anyone from working on it, but could see that a potential awardee would want to know about it. The Licensing and Patenting Manager, Whitney Blair at the Office of Technology Transfer (TTO) at NIH would be able to provide more details if needed on this.

Question 3: The topic description states that candidate products are to "be screened for repellent activity...using approved laboratory bioassays as suggested by CDC scientists". Could you provide a copy of the approved laboratory bioassays to us (as they may exist today)?

Answer: There isn't a copy or anything written up officially. To provide clarification on "approved laboratory bioassays," this is defined as using EPA approved laboratory assays (please visit www.epa.gov for more information) or laboratory bioassays demonstrated in peer-reviewed scientific journals.

Question 4: Based on the short description contained in the program solicitation, we noticed that both plant derived nootkatone and fermentation derived nootkatone are to be studied. Is the purpose of using both sources of noootkatone to compare the two head to head to see which is better? Is the use of plant derived nootkatone required?

Answer: There are many formulations so to speak of nootkatone, it can be obtained naturally from citrus products or "plant-derived", it can be synthesized, and it can be made via special yeast fermentation processes. We mentioned two different methods only as meaning it can be one or the other or one of many. There does not need to be a direct comparison of different sources of nootkatone. If it is "pure" than nootkatone is nooktatone regardless of the source.

Question 5: The solicitation describes the goal and deliverables for a formulation of nootkatone in soaps and lotions, however, there is a mention in the Phase I Activities and Expected Outcomes that once candidate products are formulated they will be screened for repellency properties against nymphal deer ticks using approved laboratory bioassays as suggested by CDC scientists. Is the overall goal of this solicitation to only develop formulations of nootkatone or is it to develop formulations <u>and</u> to perform insect repellency testing of the formulations as well? May we have the list of approved laboratory bioassays as suggested by CDC scientist?

Answer: The goal would be to develop formulations of nootkatone. That in its self will be significant. However, it is in our best interest in this case to have some initial screening and testing done to determine efficacy so as to be able to provide evidence for a potential phase II award.

Question 6: If the goal of the solicitation is to deliver both a formulation and to perform the testing of the formulation, what are the testings ("approved laboratory bioassays") that will be performed so that the developed formulation can match up to these testing parameters?

Answer: CDC does not have its own "approved" tests or bioassays. It would be best for applicants to perform tests as per the literature, peer-reviewed journals, and tests as suggested or approved by EPA website.

Question 7: Is the applicant responsible for performing the insect repellency testing on the ticks using the nootkatone formulations?

Answer: Yes.

Question 8: Is the basis of the planned studies with the lotions and soaps, etc. to evaluate

differences in formulations (e.g. comparison of efficacy between soaps and lotions), or to compare the differences between different formulations of the same type (e.g. comparison of efficacy of lotion formulation #1 against lotion formulation #2)?

Answer: Ideally we would want to see the development of formulations of soaps and lotions and then evaluate the efficacy against ticks, etc. There could be multiple formulations of each with varying concentrations of active ingredient. The tests would also hopefully show what concentration is effective at either repelling or killing or both.

Question 9: Assuming the insect control studies will be carried out by CDC:

a) **We really need to know how many tests will be performed for each formulation, and the quantity of material required for each test. For example, it would be helpful if you could tell us that you would like a quantity of xx bottles, each containing xx mls. of xx% nootkatone in lotion formulation. Same with soaps, and sprays.**
b) **It would be helpful to know how each type of sample will be used so that we can better understand the best type of formulation required for each sample. For example, can you tell us how the soaps will be tested, how the lotions will be tested, etc.**
c) **Are you seeking multiple formulations for each product type (e.g. XX different formulations of lotions, XX different formulations of sprays, etc.). If so, how many different formulations are required?**
d) **Will you also require control material (e.g. preparation of lotion formulation, but without nootkatone)? If so, how much?**
e) **For the soap formulation, would this be a liquid soap?**

Answer: Formulations would not be sent to CDC for testing. The awardee is to do the testing independent of CDC and at their facilities.

Question 10: What are the tasks you need to be done?

Answer: See the "Project Goal" & "Phase I Activities and Expected Outcomes" sections in the solicitation.

Question 11: Is there any places you like us to work with?
Answer: It is the applicant's decision to decide with whom they choose to work/subcontract.

Topic 037: Development of a Rapid Test for detection hepatitis C core antigen in clinical samples

Question 1: How long should the HCV core antigen assay be to be considered rapid?

Answer: Up to a maximum of 30-45 min.

Question 2: What kind of test is desired? A point of care test or automated laboratory test?

Answer: A point-of-care test is desired.

Question 3: May we start any work prior to funding decision using our company's resources?

Answer: CDC can't authorize or commit any work on a contract prior to the technical evaluation and completion of the acquisition process.

Topic 038: Development of a Laboratory Test for Detection of Serum Biomarkers Associated with Hepatocellular Carcinoma

Question 1: The solicitation states "*Identify a panel of biomarkers that have specific association with HCC – these may include all or some of the following markers - Glypican 3 (GPC3), Golgi membrane protein 1 (GP73), fucosylated kininogen (Fc-Kin), dickkopf WNT signaling pathway inhibitor 1 (DKK1) and Des-gamma carboxyprothrombin (DCP).*"

We would like to know if the selection of biomarkers is restricted to those listed or can alternative markers be proposed?

Answer: The selection of biomarkers is not restricted to those listed; alternative markers can also be proposed.

Topic 039: Text my EOB: The Innovative Delivery of Confidential Medical Information

Question 1: Is a test of the system in an African community acceptable, or would a U.S.-based test be preferred?

Answer: In rare and unique circumstances, for example, if a supply or material or the study design (e.g., patient population) is not available in the United States, CDC may allow a small portion of the research /R&D work to be performed by a foreign organization. However, foreign investigators must come to the United States to perform the work. Foreign involvement will be

considered on a case-by-case basis and must be thoroughly justified in the application. Whenever possible, non-SBIR funds should be used for other work outside of the United States that is necessary to the overall completion of the project.

Question 2: What are the data collection expectations during Phase 1? For this solicitation, what would meet feasibility requirements? Background: Under the description of "Project Goal" it states: "During Phase I, a feasibility study for sending EOBs via text messaging or other mobile means is expected." However, towards the end of that same paragraph the last line says "Phase I is not a data collection phase; rather, it is a critical first step to addressing this solution as the details of the solution must be informed by relevant stakeholders before development can begin."

Answer: The products of phase 1 of this project will be used to inform stakeholders about the feasibility of sending EOBs via text messaging or other mobile means and will not be used for research purposes. Thus, this project will not entail data collection.

Question 3: For this contract do I need consider clinical trials or we work with your institute?

Answer: The contract will be with CDC.

Topic 040: Development of a Mobile Application for Homeless Youth and Providers

Question 1: Do you have a preferred location for a test of the system?

Answer: The applicant makes that decision.

Topic 086: Tools for Educating Children about Clinical Research

Question 1: Does the Phase I research require a study (to evaluate the proposed tool) with pediatric population? (We are somewhat confused as Section 4.9 of the instruction says that such studies are not practical in Phase I)

Answer: Section 4.9 states" it is not practical since Phase I is normally 6 months" however Phase I for this topic was purposefully designed with a period of performance of 1 year to accommodate an evaluation element. If offerors receive an award, they will be responsible for submitting the necessary documentation to obtain OMB clearance and conduct their evaluations before the end of Phase I. The evaluation may involve children, parents, educators or others as appropriate.

Topic 327: Reformulation of Failed Chemotherapeutic Drugs

Question 1: Does the formulation technology have to be innovative or is a novel and innovative drug formulated with a sophisticated but established formulation technology sufficient?

Answer: In order to be responsive to topic 327, it is not necessarily a requirement that the platform is novel. The focus of the announcement is on reformulation of the drug, not necessarily developing new formulation strategies; therefore, reformulation using a sophisticated but established technology would be considered responsive. Please note, however, that one of the factors used for evaluating Phase I proposals is: "The potential of the proposed research for technological innovation."

Question 2: Can you provide the list of available failed chemotherapeutic drugs and why it failed?

Answer: The NCI is not providing a list of failed chemotherapeutic drugs for development under this topic. The offeror is responsible for identifying and selecting an appropriate small-molecule chemotherapeutic drug (i.e., the active pharmaceutical ingredient [API]) proposed for reformulation.

Topic 332: Development of Radiation Modulators for Use During Radiotherapy

Question 1: Is it necessary to have preliminary in vivo tox studies showing that the radiomodulator is not sensitized to healthy cells?

Answer: It is not necessary to have preliminary data prior to submission of the proposal. But it is a good idea to include a plan for getting that data during the course of your Phase I. If for some reason, you believe you do not need to do those experiments, include a valid rationale to support your belief.