AMENDMENT OF BROAD AGENCY ANNOUNCEMENT

BAA Number N44CM47014-11
Amendment Number: 1

AMENDMENT ONE (1)

Issued by:

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Broad Agency Announcement Number:

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NCI Point of Contact:

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The hour and date specified for receipt of Offers remains unchanged, 3:00 PM Eastern Prevailing 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 ANNOUNCMENT AMENDMENT

The purpose of this amendment is to (a) correct the due date for questions on the face page, (b) update the hyper-links throughout the solicitation, and (c) change the method of selection & evaluation criteria to include cost. Accordingly, Broad Agency Announcement N44CM47014-11 is revised as follows:

Face Page (Page 1), Item 4, is revised to make the following correction:

[X] Yes, See part 1.2 on page 3

Face Page (Page 1), Item 8, is revised to make the following correction:

All questions must be received by 12 noon EST on January 16, **2015** to allow adequate time to prepare and issue responses prior to the receipt of proposals. Questions received after that time and date will not be answered. All questions must be submitted in writing to ncioasbir@mail.nih.gov. No inquiries submitted via E-Mail to any other address will be answered.

Section 1.5.1 General Definitions is revised to replace the following links:

The SBA Policy Directive from the first paragraph (Page 4): http://www.sbir.gov/about/about-sbir#policy

Item (i) Small Business Concern (SBC)(Page 5). A concern that meets the requirement set forth in 13 C.F.R. §121.702 (available at http://www.ecfr.gov/cgi-bin/text-idx?SID=e8aeccb15813526381feceee63976131&node=se13.1.121_1702&rgn=div8)

Section 3.1.16 Institutional Responsibility Regarding Investigator Conflicts of Interest (Page 17), is revised to replace the link with:

http://www.ecfr.gov/cgi-bin/text-idx?tpl=/ecfrbrowse/Title45/45cfr94_main_02.tpl

Section 3.6.1.5.14 Human Subjects, is revised to replace the links in the following subsections:

a. Human Subjects Decision Chart Reference
http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html (Page 25)
b. Notice to Offerors of Requirements of 45 CFR Part 46, Protection of Human Subjects, HHSAR 352.270-4(a) (January 2006)
5. In accordance with 45 CFR Part 46, prospective Contractors being considered for award shall be required to file with OHRP an acceptable Assurance of Compliance with the regulations, specifying review procedures and assigning responsibilities for the protection of human subjects. The initial and continuing review of a research project by an institutional review board shall assure that: the rights

and welfare of the human subjects involved are adequately protected; the risks to the subjects are reasonable in relation to both the potential benefits, if any, to the subjects and the importance of the knowledge to be gained; and informed consent will be obtained by methods that are adequate and appropriate. HHS regulations for the protection of human subjects (45 CFR Part 46), information regarding OHRP registration and assurance requirements/processes, and OHRP contact information can be accessed at the OHRP Web site (at http://www.hhs.gov/ohrp/index.html Page 26).

c. **Instructions to Offerors Regarding Protection of Human Subjects remains unchanged.**

d. **Required Education in the Protection of Human Research Participants**

NIH policy requires education on the protection of human subject participants for all investigators submitting NIH proposals for contracts for research involving human subjects. This policy announcement is found in the NIH Guide for Grants and Contracts Announcement dated June 5, 2000 at the following website: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html (Page 28). Offerors should review the policy announcement prior to submission of their proposals as certification of course completion will be a deliverable of a resultant contract. The following is a summary of the Policy Announcement:

For any solicitation for research involving human subjects, the Offeror shall provide in its technical proposal the following information: (1) a list of the names of the principal investigator and any other individuals proposed under the contract who are responsible for the design and/or conduct of the research; (2) the title of the education program completed(or to be completed prior to the award of the contract) for each named personnel; (3) a one sentence description of the program(s) listed in (2) above. This requirement extends to investigators and all individuals responsible for the design and/or conduct of the research who are working as subcontractors or consultants under the contract. Curricula that are readily available and meet the educational requirement include the NIH Office of Extramural Research (OER) on-line tutorial, entitled "Protecting Human Research Participants" at: http://phrp.nihtraining.com. This course is also available in Spanish under the title "Protección de los participantes humanos de la investigación" at: http://pphi.nihtraining.com. The Offeror may take the tutorials on-line or download the information in PDF form at no cost. The University of Rochester has made its training program available for individual investigators. Completion of this program will also satisfy the educational requirement. The University of Rochester manual, entitled, "Protecting Study Volunteers in Research," can be obtained through Centerwatch, Inc. at: http://store.centerwatch.com/p-316-protecting-study-volunteers-in-research-fourth-edition.aspx (Page 29). **Certificate of Completion from the online tutorial is required prior to contract award.**

e. **Inclusion of Women and Minorities in Research Involving Human Subjects remains unchanged.**

f. **Inclusion of Children in Research Involving Human Subjects**

It is NIH policy that children (defined below) shall be included in all human subjects research, including, but not limited to, clinical trials, conducted under a contract funded by the NIH, unless there are clear and compelling reasons not to include them. (See examples of Justifications for Exclusion of Children below). For the purposes of this policy, contracts involving human subjects include categories that would otherwise be exempt from the DHHS Policy for Protection of Human Research Subjects (sections 101(b) and401(b) of 45 CFR 46), such as surveys, evaluation of educational interventions, and studies of existing data or specimens that should include children as participants. This policy applies to both domestic and foreign research contracts.

For purposes of this policy, a child is defined as an individual under the age of 21 years.

All Offerors proposing research involving human subjects should read the "NIH Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects" which was published in the NIH Guide for Grants and Contracts on March 6,1998 and is available at the following URL address: http://grants.nih.gov/grants/guide/notice-files/not98-024.html (Page 32)

Research Involving Prisoners as Subjects

a. HHS Regulations at 45 CFR Part 46, Subpart C provide additional protections pertaining to biomedical and behavioral research involving prisoners or those individuals who, during the period of the contract become prisoners, as subjects. These regulations also set forth the duties of the Institutional Review Board (IRB) where prisoners are involved in their search. HHS funded research involving prisoners as subjects may not proceed until the Office for Human Research Protections (OHRP) issues approval, in writing, as required by 45 CFR 46.306(a)(2). In addition, OHRP Guidance on the Involvement of Prisoners in Research may be found at:
http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.305 (Page 34)
b. HHS Waiver for Epidemiological Research Involving Prisoners as Subjects
On June 20, 2003 the Secretary of HHS waived the applicability of certain provisions of Subpart C of 45 CFR Part 46, (Additional DHHS Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects) to specific types of epidemiological research involving prisoners as subjects.
The applicability of 45 CFR 46.305(a)(1) and 46.306(a)(2) for certain epidemiological research conducted or funded by DHHS is waived when:

1. The sole purposes are:
   - to describe the prevalence or incidence of a disease by identifying all cases, or
   - to study potential risk factor associations for a disease, and
2. The Institution responsible for the conduct of the research certifies to the OHRP that the Institutional Review Board (IRB) approved the research and fulfilled its duties under 45 CFR 46.305(a)(2 7) and determined and documented that:
   - the research presents no more than minimal risk, and
   - no more than inconvenience to the prisoner subjects, and
   - prisoners are not a particular focus of the research. For more information about this Waiver see http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html

g. **Research Involving Human Fetal Tissue**
Human Fetal Tissue means tissue or cells obtained from a dead human fetus, including human embryonic stem cells, human pluripotent stem cells and human embryonic germ cells.
The governing federal statute is the Public Health Service Act, 42 U.S.C. 289g 1 and 289g2. Implementing regulations and guidance for conducting research on human fetal tissue may be found at 45 CFR 46, Subpart B and http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html and any subsequent revisions to this NIH Guide to Grants and Contracts ("Guide") Notice.

h. **Human Embryonic Germ Cell (HEGC) Research**
a. Guidelines.
Research use of human embryonic germ cells derived from fetal tissue with Federal funds requires review of compliance with the NIH Guidelines for Research Using Human Pluripotent Stem Cells (http://stemcells.nih.gov/news/newsarchives/pages/stemcellguidelines.aspx Page 34) (only the information regarding human embryonic germ cells is relevant). Embryonic germ cells are pluripotent stem cells derived from human embryos. See NIH Guide for Grants and Contracts Notice NOT OD 02 049, requiring that Offerors/contractors submit certain documents to the Human Pluripotent Stem Cell Review Group(HPSCRG), which will be reviewed in a public meeting. Research using human embryonic germ cells may not be performed prior to approval by the HPSCRG.
All Offerors should read the "NIH Guidelines"
(http://stemcells.nih.gov/news/newsarchives/pages/stemcellguidelines.aspx Page 34) if they either: (1) propose to respond to the Statement of Work requirements by conducting research that uses human embryonic germ cells or, (2)are responding to a Statement of Work that requires the use of human embryonic germ cells.

Offerors may obtain copies of these Guidelines from the website above or from the contact person listed in this solicitation.

b. Procedure for Review by Human Pluripotent Stem Cell Review Group (HPSCRG)
The _____ has determined that human embryonic germ cells are required to be used for the conduct of this research. The Offeror shall submit an original and two copies of the documentation and assurances that address the areas covered the "Procedures for Submission of Compliance Documents to the Human Pluripotent Stem Cell Review Group (HPSCRG) for the Research Use of Human Embryonic Germ Cells," at:
(http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-049.html Page 35) as a separate attachment in its proposal. Prior to any award made under this solicitation, the documentation and assurances will be subject to review by the HPSCRG, which meets in a public meeting. No research involving the use of human embryonic germ cells may begin prior to HPSCRG approval.

Offerors are encouraged to review issues pertaining to informed consent processes described in Section II.B.2.b of the NIH Guidelines, at:
(http://stemcells.nih.gov/news/newsarchives/pages/stemcellguidelines.aspx (page 35).
Offerors should also review the March 19, 2002, DHHS Office of Human Research Protection's document titled, "Guidance for Investigators and Institutional Review Boards Regarding Research Involving Human Embryonic Stem Cells, Germ Cells, and Stem Cell Derived Test Articles,"(
http://stemcells.nih.gov/news/newsarchives/pages/stemcellguidelines.aspx (Page 35)

OR

b. Procedure for Review by Human Pluripotent Stem Cell Review Group (HPSCRG)

If, in response to the solicitation, the Offeror proposes to use human embryonic germ cells, it shall submit, as a separate attachment to its proposal, an original and two copies of the documentation and assurances that address the areas covered in the "Procedures for Submission of Compliance Documents to the Human Pluripotent Stem Cell Review Group (HPSCRG) for the Research Use of Human Embryonic Germ Cells" at:
(http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-049.html Page 35).
Prior to any award made under this solicitation, the documentation and assurances will be subject to review by the HPSCRG, which meets in a public meeting. No research involving the use of human embryonic germ cells may begin prior to HPSCRG approval.
Offerors are encouraged to review issues pertaining to informed consent processes described in Section II.B.2.b of the NIH Guidelines. Offerors should also review the March 19, 2002, DHHS Office of Human Research Protection's document titled" Guidance for Investigators and Institutional Review Boards Regarding Research Involving Human Embryonic Stem Cells, Germ Cells, and Stem Cell Derived Test Articles," at
(http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-044.html Page 35)

OR

b. Procedure for Review by Human Pluripotent Stem Cell Review Group (HPSCRG)

The _____ has determined that human embryonic germ cells are required to be used for the conduct of this research. The Offeror shall confirm in its proposal that it plans to use human embryonic germ cells as a part of its research. If the Offeror receives a contract award, the Contractor may not perform any research using human embryonic germ cells until the Human Pluripotent Stem Cell Review Group(HPSCRG) has reviewed and approved the documentation furnished as prescribed in the "Procedures for Submission of Compliance Documents to the Human Pluripotent Stem Cell Review Group (HPSCRG) for the Research Use of Human Embryonic Germ Cells"
(http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-049.html)and the

Contracting Officer has notified the Contractor of the approval in writing.
Offerors are encouraged to review issues pertaining to informed consent processes described in Section II.B.2.b of the NIH Guidelines at:
(http://stemcells.nih.gov/news/newsarchives/pages/irpnotice_011601.aspx).Offerors should also review the March 19, 2002, DHHS Office of Human Research Protection's document titled "Guidance for Investigators and Institutional Review Boards Regarding Research Involving Human Embryonic Stem Cells, Germ Cells, and Stem Cell Derived Test Articles," at:
(http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-044.html)
The resultant contract will be divided into discrete phases or option periods. During Option Period(s)/Phase(s) * of the contract, the Contractor shall submit the original and two copies of the required documentation and assurances that address the areas covered in "Procedures for Submission of Compliance Documents to the Human Pluripotent Stem Cell Review Group (HPSCRG) for the Research Use of Human Embryonic Germ Cells," at:
(http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-049.html)to the Contracting Officer. This documentation will be forwarded for review and approval to the HPSCRG.
If the HPSCRG disapproves the documentation presented by the Contractor, the Contracting Officer may elect to either terminate the contract in accordance with the Termination for Convenience clause of the contract OR determine not to exercise subsequent option(s) as appropriate based the terms of the specific contract. Otherwise, when the HPSCRG approves the documentation, the Contracting Officer will notify the Contractor in writing that research using the human embryonic germ cells may commence.
Research involving the use of human embryonic germ cells shall not be conducted under the contract until the HPSCRG review and approval have been obtained, and the Contracting Officer has provided written notice of such approval to the Contractor.

OR

b. Procedure for Required Review by Human Pluripotent Stem Cell Review Group(HPSCRG)

If the Offeror intends to fulfill the requirements of the Statement of Work by performing research using human embryonic germ cells, it shall so state in its proposal.
If the Offeror's proposal includes research using human embryonic germ cells and it receives a contract award, the Contractor may not perform any research using these human embryonic germ cells until the Human Pluripotent Stem Cell Review Group(HPSCRG) has reviewed and approved the documentation furnished as prescribed in "Procedures for Submission of Compliance Documents to the Human Pluripotent Stem Cell Review Group (HPSCRG) for the Research Use of Human Embryonic Germ Cells" (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-049.html)and the Contracting Officer has notified the Contractor of the approval in writing.
The resultant contract will be divided into discrete phases or option period(s). During Option Period(s)/Phase(s) * of the contract, the Contractor shall submit the original and two copies of the required documentation and assurances that address the areas covered in "Procedures for Submission of Compliance Documents to the Human Pluripotent Stem Cell Review Group (HPSCRG) for the Research Use of Human Embryonic Germ Cells," at:(
http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-049.html) to the Contracting Officer. This documentation will be forwarded for review and approval to the HPSCRG.
If the HPSCRG disapproves the documentation presented by the Contractor, the Contracting Officer may elect to either terminate the contract in accordance with the Termination for Convenience clause of the contract OR determine not to exercise subsequent option(s) as appropriate based the terms of the specific contract. Otherwise, when the HPSCRG approves the documentation, the Contracting Officer will notify the Contractor in writing that research using the human embryonic germ cells may commence.

Research involving the use of human embryonic germ cells shall not be conducted under the contract until the HPSCRG review and approval have been obtained, and the Contracting Officer has provided written notice of such approval to the Contractor.

i. **Human Embryonic Stem Cell (hESC) Research remains unchanged.**

j. **Data and Safety Monitoring in Clinical Trials**

All Offerors are directed to the full text of the NIH Policies regarding Data and Safety Monitoring and Reporting of Adverse Events that are found in the NIH Guide for Grants and Contracts Announcements at the following web sites:
http://grants.nih.gov/grants/guide/notice-files/not98-084.html
http://grants.nih.gov/grants/guide/notice-files/not99-107.html
http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-038.html

All Offerors receiving an award under this solicitation shall comply with the NIH Policy cited in these NIH Announcements and any other data and safety monitoring requirements found elsewhere in this solicitation.

The following is a brief summary of the Data and Safety Monitoring and Adverse Event Reporting Requirements:

Data and Safety Monitoring is required for every clinical trial. Monitoring shall be performed on a regular basis and the conclusions of the monitoring reported to the Contracting Officer's Representative (COR).

The type of data and safety monitoring required will vary based on the type of clinical trial and the potential risks, complexity and nature of the trial. A plan for data and safety monitoring is required for all clinical trials. A general description of a monitoring plan establishes the overall framework for data and safety monitoring. It should describe the entity that will be responsible for the monitoring, and the policies and procedures for adverse event reporting. Phase III clinical trials generally require the establishment of a Data Safety Monitoring Board (DSMB). The establishment of a DSMB is optional for Phase I and Phase II clinical trials.

The DSMB/Plan is established at the time the protocol is developed and shall be approved by both the Institutional Review Board (IRB) and the Government and in place before the trial begins. If the protocol will be developed under the contract awarded from this solicitation, a general description of the data and safety monitoring plan shall be submitted as part of the proposal and will be reviewed by the scientific review group (Technical Evaluation Panel, (TEP)) convened to evaluate the proposal.

If the protocol is developed and is included as part of the submitted proposal, a complete and specific data and safety monitoring plan shall be submitted as part of the proposal.

Monitoring Plans, at a minimum, shall include the prompt reporting of adverse events to the IRB, the NIH Office of Biotechnology Activities (OBA), and the Food and Drug Administration (FDA). Also, in the plan the Offeror should describe the frequency of reporting of the conclusions of the monitoring activities. The overall elements of each plan may vary depending on the size and complexity of the trial. The NIH Policy for Data and Safety Monitoring at http://grants.nih.gov/grants/guide/notice-files/not98-084.html describes examples of monitoring activities to be considered.
The frequency of monitoring will depend upon potential risks, complexity, and the nature of the trial; therefore a number of options for monitoring trials are available. These can include, but are not limited to, monitoring by a:

- Principal Investigator (required)
- Independent individual /Safety Officer
- Designated medical monitor
- Internal Committee or Board with explicit guidelines

- Data and Safety Monitoring Board (DSMB - required for multisite trials)
- Institutional Review Board (IRB - required)

For multi-site Phase I and Phase II trials, a central reporting entity that will be responsible for preparing timely summary reports of adverse events for distribution among sites and IRBs should be considered.

Organizations with a large number of clinical trials may develop standard monitoring plans for Phase I and Phase II trials. In this case, such organizations may include the IRB-approved monitoring plan as part of the proposal submission.

k. **Registration of and Results Reporting for Applicable Clinical Trials in ClinicalTrials.gov**

The Food and Drug Administration Amendments Act of 2007(FDAAA) at: http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/SignificantAmendmentstotheFDCAct/FoodandDrugAdministrationAmendmentsActof2007/default.htm , Title VIII, expands the National Institutes of Health's (NIH's) clinical trials registry and results database known asClinicalTrials.gov (http://www.clinicaltrials.gov/) and imposes new requirements that apply to certain applicable clinical trials, including those supported in whole or in part by NIH funds. FDAAA requires:

a. The registration of certain "applicable clinical trials" in ClinicalTrials.gov no later than 21 days after the first subject is enrolled; and

b. The reporting of summary results information (including adverse events) no later than1 year after the completion date for registered applicable clinical trials involving drugs that are approved under section 505 of the Food, Drug and Cosmetic Act (FDCA) or licensed under section 351 of the PHS Act, biologics, or of devices that are cleared under section 510k of FDCA.

The resultant contract will support one or more applicable clinical trial subject to FDAAA. The "responsible party" is the entity responsible for registering and reporting trial results inClinicalTrials.gov.

• Where the Contractor is the IND/IDE holder, the Contractor will be considered the Sponsor, therefore the "Responsible Party."

• Where there is no IND/IDE holder or where the Government is the IND/IDE holder, the Government will generally be considered the "Sponsor" and may designate the contractor's Principal Investigator (PI) as the "Responsible Party."

• For Multi-Center trials where there is no IND/IDE holder or where the Government is the IND/IDE holder, the "Responsible Party" will be designated at one site (generally the lead clinical site) and all other sites will be responsible for providing necessary data to the "Responsible Party" for reporting in the database.

Additional information is available at http://prsinfo.clinicaltrials.gov

Section 3.6.1.5.16 Research Involving Live Vertebrate Animals is revised to replace the following links:

It is intended that live vertebrate animals will be used during performance of this contract. The Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (authority derived from the Health Research Extension Act of 1985) specifies that certain information is required from Offerors in contract proposals submitted to the NIH that will use live vertebrate animals.

The following five points shall be addressed in a separate section of the Technical Proposal titled "Vertebrate Animal Section" (VAS):

a. Detailed description of the proposed use of the animals, including species, strains, ages, sex and number to be used.

b. Justification for the use of animals, choice of species, and numbers to be used. c. Information on the veterinary care of the animals.

d. Description of procedures for minimizing discomfort, distress, pain and injury.
e. Method of euthanasia and the reasons for the selection.

A concise (no more than 1-2 pages), complete description addressing these five points shall be provided. The description shall be cohesive and include sufficient information to allow evaluation by reviewers and NIH staff. For more discussion regarding the five points in the VAS, see NIH Guide Notice NOT-OD-10-049 at: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-049.html .

If a subcontract is proposed, an InterInstitutional Agreement shall be established with the Office of Laboratory Animal Welfare (OLAW) prior to award.

The Contract Proposal VAS Worksheet is provided as an Attachment in PART 9 of this solicitation to assist in the preparation of the VAS as part of the Technical Proposal. It can be accessed at: http://grants.nih.gov/grants/olaw/VAScontracts.pdf .

Section 3.6.1.5.17 Obtaining and Disseminating Biomedical Research Resources is revised to replace the following links:

As a public sponsor of biomedical research, the National Institutes of Health (NIH) has a dual interest in accelerating scientific discovery and facilitating product development. Intellectual property restrictions can stifle the broad dissemination of new discoveries and limit future avenues of research and product development. At the same time, reasonable restrictions on the dissemination of research tools are sometimes necessary to protect legitimate proprietary interests and to preserve incentives for commercial development. To assist NIH contractors achieve an appropriate balance, the NIH has provided guidance in the form of a two- part document, consisting of Principles setting forth the fundamental concepts and Guidelines that provide specific information to patent and license professionals and sponsored research administrators for implementation.

The purpose of these Principles and Guidelines is to assist NIH funding recipients in determining: 1) Reasonable terms and conditions for making NIH-funded research resources available to scientists in other institutions in the public and private sectors (disseminating research tools); and 2) Restrictions to accept as a condition of receiving access to research tools for use in NIH-funded research (acquiring research tools). The intent is to help recipients ensure that the conditions they impose and accept on the transfer of research tools will facilitate further biomedical research, consistent with the requirements of the Bayh-Dole Act and NIH funding policy.

This policy, entitled, "SHARING BIOMEDICAL RESEARCH RESOURCES: Principles and Guidelines for Recipients of NIH Research Grants and Policy," (Federal Register Notice, December 23, 1999[64 FR 72090] will be included in any contract awarded from this solicitation. It can be found at the following website: http://grants.nih.gov/grants/sharing.htm.

1. **Sharing Research Data**
[Note: This policy applies to **all** NIH contracts, regardless of dollar value, that are expected to generate research data.]

The NIH endorses the sharing of final research data to expedite the translation of research results into knowledge, products, and procedures to improve human health. This contract is expected to generate research data. Therefore, the Offeror shall submit a plan in its technical proposal for data sharing or state why data sharing is not possible. If data sharing is limited, the Offeror should explain such limitations in its data sharing plan. NIH's data sharing policy may be found at the following Web site:

http://grants.nih.gov/grants/policy/data_sharing/

[If the resultant contract is part of a collaborative program involving multiple sites, the data sharing will be governed by a dissemination plan to be developed jointly following award. Offerors shall include in their proposals a statement of willingness to work collaboratively after award with the other funded sites to prepare a joint dissemination plan. Coordinating Center proposals should describe methods to coordinate the dissemination planning and implementation. The Coordinating Center shall include a budget and justification for any additional costs of this collaborative effort.]

2. **Sharing of Model Organisms for Biomedical Research**
The NIH Research Tools Policy (http://grants.nih.gov/grants/sharing.htm) also referred to as NIH Principles and Guidelines for Sharing of Biomedical Resources: Final Notice, December 1999, supports the concept of timely sharing and distribution of research resources. In accordance with NIH Guide Notice NOT-OD-04-042 at:(http://grants.nih.gov/grants/guide/notice-files/NOT-OD-04-042.html), dated May 7, 2004,and the September 10, 2004 extension of this policy NOT-OD-04-066 at:(http://grants.nih.gov/grants/guide/notice-files/NOT-OD-04-066.html),the NIH provides further sharing guidance with particular attention on model organisms for biomedical research. Such organisms include, but are not limited to: mammalian models such as the mouse and rat, and non-mammalian models, such as budding yeast, social amoebae, round worm, fruit fly, zebra fish, and frog. Research resources to be shared include genetically modified or mutant organisms, sperm, embryos, protocols for genetic and phenotypic screens, mutagenesis protocols, and genetic and phenotypic data for all mutant strains.

Offerors shall include in their technical proposal a description of a specific plan for sharing and distributing unique model organism research resources generated using NIH funding so that other researchers can benefit from these resources, OR provide appropriate reasons why such sharing is restricted or not possible. A reasonable time frame for periodic disposition of material and associated data shall be specified in the proposal. In addition, the plan shall address if, or how, Offerors will exercise their intellectual property rights while making model organisms and research resources available to the broader scientific community. At a minimum, the plan should address the following:
• Will material transfers be made with no more restrictive terms than in a Simple Letter Agreement (SLA) at: http://www.ott.nih.gov/sites/default/files/documents/pdfs/slaform.pdf ; for the transfer of materials or the Uniform Biological Material Transfer Agreement (UBMTA) (http://www.autm.net/UBMTA/8847.htm)
• How will inappropriate "reach-through" requirements (as discussed in the NIH Research Tools Policy) on materials transferred be discussed?
• How will technologies remain widely available and accessible to the research community, for example, if any intellectual property rights arise for which a patent application may be filed?
Offerors may request funds in their cost proposal to defray reasonable costs associated with sharing materials or data or transfer of model organisms and associated data to appropriate repositories.

3. **Data Sharing Policy for Genome-Wide Association Studies**
NIH is interested in advancing genome-wide association studies (GWAS) to identify common genetic factors that influence health and disease through a centralized GWAS data repository. For the purposes of this policy, a genome-wide association study is defined as any study of genetic variation across the entire human genome that is designed to identify genetic associations with observable traits (such as blood pressure or weight),or the presence or absence of a disease or condition.
All Offerors proposing a genome-wide association study are expected to provide a plan for submission of GWAS data to the NIH-designated GWAS data repository, or provide an appropriate explanation why submission to the repository is not possible. Contractors submitting GWAS data are expected to:
• Provide descriptive information about their studies;
• Submit coded genotypic and phenotypic data to the NIH GWAS data repository; and
• Submit a certification that the institution or organization has reviewed and approved submission to the NIH, noting any limitations on data use based on the relevant informed consents and providing assurance

that all data are submitted to the NIH in accord with applicable laws and regulations and that the identities of research participants will not be disclosed to the NIH GWAS data repository and an IRB and/or Privacy Board, as applicable, has reviewed and verified that:

- The submission of data to the NIH GWAS data repository and subsequent sharing for research purposes are consistent with the informed consent of study participants from whom the data were obtained;
- The investigator's plan for de-identifying datasets is consistent with the standards outlined above;
- It has considered the risks to individuals, their families, and groups or populations associated with data submitted to the GWAS data repository; and
- The genotype and phenotype data to be submitted were collected in a manner consistent with 45 C.F.R. Part 46.

Contractors requesting access to GWAS data in the NIH repository are expected to:

• Submit a data access request, including a brief description of the proposed research and a Data Use Certification that is co-signed by the designated Institutional Official(s) at their sponsoring institution;
• Use the data only for the approved research project described in the data access request;
• Protect data confidentiality;
• Not attempt to use the requested datasets to re-identify or contact individual study participants;
• Retain control of the data and not distribute it to any entity or individual not covered in the data access request;
• Ensure that data security measures are in place;
• Notify the appropriate Data Access Committee of policy violations; and
• Submit annual progress reports detailing significant research findings.

Additionally, Contractors requesting access to the data are also expected to abide by the dbGaP Approved User Code of Conduct (https://dbgap.ncbi.nlm.nih.gov/aa/GWAS_Code_of_Conduct.html).
Data repository management (submission and access) is governed by the Policy for Sharing of Data Obtained in NIH Supported or Conducted Genome-Wide Association Studies, NIH Guide NOT-OD-07-088 located at: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-088.html For additional information see: http://gwas.nih.gov/ .

Section 3.7.1(3) Required Certifications (Page 44), the link is replaced with the following:
http://grants.nih.gov/grants/forms.htm

Section 3.7.4(10)(a)(4) Indirect Costs (Page 52), the link is replaced with the following:
http://oamp.od.nih.gov/sites/default/files/appendix_q_hhs_contracting_guide.pdf

Section 3.7.4(12) Subcontractors (Page 55), is revised to remove the last paragraph and now reads as follows:

If subcontractors are proposed, please include a commitment letter from the subcontractor detailing:

a. Willingness to perform as a subcontractor for specific duties (list duties).
b. What priority the work will be given and how it will relate to other work.
c. The amount of time and facilities available to this project.
d. Information on their cognizant field audit offices.
e. How rights to publications and patents are to be handled.
f. A complete cost proposal in the same format as the Offeror's cost proposal.

Section 4, METHOD OF SELECTION AND EVALUATION CRITIRIA, 4.1.1 General (Page 56), is revised to make the following correction:

Proposals will be evaluated against five factors. The factors in order of importance are: technical, areas of high program relevance, program balance (balance among areas of research), availability of funds, **and cost**. Cost is less important to the overall contract award decision. The Government intends to make award(s) to that Offeror(s) whose proposal provides the best overall value to the Government.

Section 4.2.2 Live Vertebrate Animals Evaluation (Page 61) is revised to replace the link with the following:
http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-049.html

Section 5.2 (b)(2) Reporting of Financial Conflict of Interest (FCOI)(Page 65) is revised to replace the link with the following:
http://www.ecfr.gov/cgi-bin/text-idx?tpl=/ecfrbrowse/Title45/45cfr94_main_02.tpl
Section 5.9 Awardee Commitments (Page 68) is revised to replace the link with the following:
http://oamp.od.nih.gov/dgs/general-clauses/clause-details/SBIR2

Section 5.10 Limitations on the Use of Appropriated Funds is revised as follows to replace links:

NIH POLICY ON ENHANCING PUBLIC ACCESS TO ARCHIVED PUBLICATIONS RESULTING FROM NIH-FUNDED RESEARCH (Page 69)
NIH-funded investigators shall submit to the NIH National Library of Medicine's (NLM) PubMed Central (PMC) an electronic version of the author's final manuscript, upon acceptance for publication, resulting from research supported in whole or in part with direct costs from NIH. NIH defines the author's final manuscript as the final version accepted for journal publication, and includes all modifications from the publishing peer review process. The PMC archive will preserve permanently these manuscripts for use by the public, health care providers, educators, scientists, and NIH. The Policy directs electronic submissions to the NIH/NLM/PMC: http://www.pubmedcentral.nih.gov.

Additional information is available at http://grants.nih.gov/grants/guide/notice-files/not-od-08-033.html.

INSTITUTIONAL RESPONSIBILITY REGARDING INVESTIGATOR FINANCIALCONFLICTS OF INTEREST (Page 70)
The Institution (includes any contractor, public or private, excluding a Federal agency) shall comply with the requirements of 45 CFR Part 94, Responsible Prospective Contractors, which promotes objectivity in research by establishing standards to ensure that Investigators (defined as the project director or principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded under NIH contracts, or proposed for such funding, which may include, for example, collaborators or consultants) will not be biased by any Investigator financial conflicts of interest. 45 CFR Part 94 is available at the following Web site: http://www.ecfr.gov/cgi-bin/text-idx?tpl=/ecfrbrowse/Title45/45cfr94_main_02.tpl

Section 7 Scientific and technical Informational Sources (Page 73) is revised to replace the following link:
National Technology Transfer Center
Wheeling Jesuit College
1-800-678-6882
http://develop.nttc.edu/

Section 8 Research Topics is revised as follows:

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

Topic 317 Wound Healing Preparations Incorporating Nitric Oxide-releasing Materials (NIH Technology Transfer) (Page 81) is revised to replace links as follows:

Budget (total costs): $1,500,000 for two (2) years.

It is strongly suggested that proposals adhere to the above budget amounts and project periods. Proposals with budgets exceeding the above amounts and project periods may not be funded.

For frequently asked questions on this contract topic see:
http://sbir.cancer.gov/funding/contracts/fy2013_faq.asp

Summary:
Non-healing wounds can pose significant problems for cancer patients (e.g., in cases where multiple operations are required for local recurrence, when large wounds are slow to close, and especially when patients receive radiation at sites requiring surgery). In addition, the effects of chemotherapy, nutritional deficits along with co-morbidities (e.g., diabetes), and infections can complicate wound healing. Therefore, the cancer patient population has the potential for non-healing wounds due to the nature and effects of the oncologic disease process and its treatments
(http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2206003/)Improved methods are thus needed for treating non- healing wounds that often result in lengthy hospital stays, application of multiple types of dressings and ointments, and hyperbaric methods.

Nitric oxide (NO) is an important bio-signaling molecule whose role has been extensively recognized in the body's endogenous immune, inflammatory, and tissue regenerative responses. Therapeutic application of exogenous topical NO-generating agents has been shown to provide powerful, broad-spectrum antimicrobial action, and NO is capable of providing numerous wound-healing benefits if delivered at the proper concentrations. However, since NO is an easily oxidized gas, controlled topical delivery of NO to a desired area is difficult. The National Cancer Institute (NCI)
has developed a family of polymers based on poly(acrylonitrile) that are capable of storing NO bound in a stable chemical functionality, called a diazeniumdiolate group, and releasing NO under aqueous conditions. The next logical step in the utilization of these materials for biomedical applications is the incorporation of these NO-releasing poly(acrylonitrile)-based compositions into suitable, biocompatible dressings for application to wounds to fight infection, modulate inflammation, and promote angiogenesis and collagen synthesis in order to accelerate wound closure and/or otherwise improve functional outcomes.
This invention is the subject of issued patents US 7,968,664 and US 8,093,343, and HHS Reference Number E-188-2004.

Project Goals:
The ultimate goal of this effort is to develop a commercially viable wound-healing dressing, utilizing this NCI-developed technology, to alleviate the suffering and costs caused by non-healing wounds, thereby establishing a precedent for supportive care for cancer while quickly creating a product of merit. The short-term goal of this project is to develop a prototype of such a dressing and to provide data that clearly demonstrate the potential of this stable NO-releasing material/formulation. The work scope may include design and fabrication of the material with *in vitro* evaluation (e.g., product stability testing) and preliminary *in vivo* assessment of its efficacy and final prototype development. These data will support the continued development of the experimental

medical device to the point of filing an Investigational Device Exemption (IDE). The long-term goal of this topic is to enable a small business to bring a fully developed product incorporating NCI's NO-releasing polymer technology to the clinic and the market.

The dressing to be developed under this contract should demonstrate the ability to maintain the stability of the diazeniumdiolate group during storage and sterilization, and to release NO when triggered by any mechanism related to wound contact (e.g., thermal or aqueous stimuli, biochemical interaction, etc.), or triggered by the health care provider (e.g., light source, chemical mixing, etc.). Since one of the major potential benefits of sustained and controlled release of therapeutic NO is the reduced frequency with which the care provider must contact the wounded skin to apply therapeutics and change the dressing, any stable, NO-releasing formulation will be considered including, but not limited to, fabric-based "traditional" dressings incorporating poly(acrylonitrile) as one of the textile components, hydrogels, creams, gels, nanomaterials, meshes, films, coatings, etc.

This is an NIH TT (Technology Transfer) contract topic from the NCI. This is a program whereby inventions from the NCI Intramural Research Program (Center for Cancer Research, CCR) are licensed to qualified small businesses with the intent that those businesses develop these inventions into commercial products that benefit the public. The contractor funded under this contract topic shall work closely with the NCI CCR inventors of this technology. The inventors will provide assistance in a collaborative manner with reagents and discussions during the entire award period. Between the time this contract topic is published and the time an offeror submits a contract proposal for this topic, no contact will be allowed between the offeror and the NCI CCR inventors. However, a pre-submission public briefing and/or webinar will be given by NCI staff to explain in greater detail the technical and licensing aspects of this program (for further information, see http://sbir.cancer.gov/news/upcoming/). In addition, a list of relevant technical, invention, and licensing-related questions and answers (including those from the public briefing) will be posted, maintained, and updated online (http://sbir.cancer.gov/news/upcoming/) during this time period.

The awarded contractor will automatically be granted a royalty-free, non-exclusive license to use NIH-owned and patented background inventions only within the scope and term of the award. However, an SBIR offeror or SBIR contractor can apply for an exclusive or non-exclusive commercialization license to make, use, and sell products or services incorporating the NIH background invention. Offerors submitting an SBIR contract proposal in response to this topic are strongly encouraged to submit concurrently an application for a commercialization license to such background inventions. Under the NIH NCI TT program, the SBIR contract award process will be conducted in parallel with, but distinct from, the review of any applications for a commercialization license.

To apply for a commercialization license to develop this NIH invention, an SBIR offeror or contractor must submit a license application to the NIH Licensing and Patenting Manager: Betty Tong Ph.D., tongb@mail.nih.gov or 301-594-
6565. Please visit http://www.ott.nih.gov/forms-model-agreements#LAP to get a pdf or word copy of the license application or to view model license agreements.

This license application provides NIH with information about the potential licensee, some of the terms desired, and the potential licensee's plans for development and/or commercialization of the invention. License applications will be treated in accordance with Federal patent licensing regulations as provided in 37 CFR Part 404. A further description of the NIH licensing process is available at http://www.ott.nih.gov/licensing-process. NIH will notify an SBIR offeror who has submitted an application for an exclusive commercialization license if another application for an exclusive license to the background invention is received at any time before such a license is granted.
Any invention developed by the contractor during the course of the NIH TT contract period of performance will be owned by the contractor subject to the terms of Section 8.5.

Phase II Activities and Expected Deliverables:

• All studies in Phase II shall be conducted with the ultimate aim of producing a product acceptable to the FDA, and shall thus follow the recommendations contained in the FDA document "Guidance for Industry: Chronic Cutaneous Ulcer and Burn Wounds-Developing Products for Treatment" published June 2006 and available for download from the FDA website http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM071324.pdf.
• Conduct appropriate stability studies, including thermal stability at sterilization temperatures and shelf life characterization
• Provide quantitative evidence of improved wound healing over the current standard-of-care
• Demonstrate capability for commercial production of the product
• Demonstrate capability to manufacture and sterilize the lead candidate in an industrial setting
• Prototype should demonstrate the ability to provide medical benefit, robust stability, and commercial potential

Topic 318 Test to predict Effectiveness of Docetaxel Treatment for Prostate Cancer (NIH Technology Transfer) (Page 83) is revised to replace links as follows:

Budget (total costs): $2,000,000 for two (2) years.

It is strongly suggested that proposals adhere to the above budget amounts and project periods. Proposals with
budgets exceeding the above amounts and project periods may not be funded.

For frequently asked questions on this contract topic see:
http://sbir.cancer.gov/funding/contracts/fy2013_faq.asp

Summary:
Over the past two years, medical oncologists have added three new therapies to the therapeutic arsenal against
Castration-Resistant Prostate Cancer (CRPC): abiraterone, Sipleucel-T, and cabazitaxel. Before approval of these
agents, docetaxel was the only life-extending therapeutic option for men with CRPC, and docetaxel remains the standard of care for men who can tolerate chemotherapy. Moreover, there are several promising agents that are likely to be FDA-approved for CRPC in coming years (i.e., MDV-3100, EPI-001, and TOK-001). Therefore, the commercial availability of a method to determine which CRPC patients will have a superior response to docetaxel
therapy (and which CRPC patients will not respond), will allow medical oncologists to consider other approved options in certain patients, thereby "personalizing" CRPC therapy.

The National Cancer Institute (NCI) has developed a genotype test that can indicate the duration of survival following docetaxel therapy in men with CRPC. The test detects a genetic variant in cytochrome P450 1B1 (*CYP1B1*3; 4326C>G*) that encodes a leucine-to-valine amino acid substitution, L432V, in the translated protein. This genetic polymorphism causes *P450 1B1* *3 to synthesize higher than normal concentrations of a reactive estrogen species (e.g., estradiol-3,4- quinone [E2-3,4Q]) that reduces docetaxel activity via two distinct mechanisms. Firstly, E2-3,4Q binds directly to docetaxel at biological pH, thereby reducing docetaxel potency. Secondly, E2-3,4Q antagonizes the mechanism of action of docetaxel (i.e., microtubule stabilization), by destabilizing the interaction between tubulin thiol groups that are required to form microtubules. Therefore, a simple genotypic test can determine whether or not a patient will respond to docetaxel, or whether treatment with other newly-approved anticancer agents is warranted. The genetic marker *CYP1B1*3* could be used as a prognostic tool to predict survival rate and propensity to respond to docetaxel treatment.

This invention is the subject of filed patent applications US20100280084A1 and EP1943358, and HHS Reference
Number E-307-2005/0.

Project Goals:
The focus of this topic is to advance development of this genetic test which would provide rapid and useful *a priori* predictions of the clinical outcome of docetaxel patients and guide the therapeutic strategy for each patient. The short-term goals of this project are to: (i) develop a rapid and reproducible assay for the CYP1B1*3 variant; (ii) provide additional preclinical evidence necessary for carrying the CYP1B1*3 genotype test into the clinical setting; and (iii) determine if cabazitaxel activity is related to the CYP1B1*3 allele and reactive estrogen species. The long-term goal of this project is obtain FDA approval for the test, to establish broader utility for the CYP1B1*3 test in treatment of other cancer types, implement the test in conjunction with alternate therapeutics that act via modulation of this estrogen responsive pathway, and to further translate the utility of the genotype test to wider clinical use. This technology, once demonstrated in the field of prostate cancer, could be applied to breast and lung cancer genetic markers that have clinical application in defining the chemotherapeutic treatment schedules for individual patients.

Phase I deliverables included technique development, further demonstration of the mechanism of CYP1B1*3 interference, validation that genotype is related to survival using retrospective CRPC patient samples, and identification of the percentage of samples with the variant. A future Phase II SBIR award would include a genotype- directed prospective clinical trial with docetaxel and/or cabazitaxel to demonstrate improved taxane outcomes in genotyped patients.

This is an NIH TT (Technology Transfer) contract topic from the NCI. This is a program whereby inventions from the NCI Intramural Research Program (Center for Cancer Research, CCR) are licensed to qualified small businesses with the intent that those businesses develop these inventions into commercial products that benefit the public. The contractor funded under this contract topic shall work closely with the NCI CCR inventor of this technology. The inventor will provide assistance in a collaborative manner with reagents and discussions during the entire award period.

Between the time this contract topic is published and the time an offeror submits a contract proposal for this topic, no contact will be allowed between the offeror and the NCI CCR inventor. However, a pre-submission public briefing and/or webinar will be given by NCI staff to explain in greater detail the technical and licensing aspects of this program (for further information, see http://sbir.cancer.gov/news/upcoming/)In addition, a list of relevant technical, invention, and licensing-related questions and answers (including those from the public briefing) will be posted, maintained, and updated online (http://sbir.cancer.gov/news/upcoming/) during this time period.
The awarded contractor will automatically be granted a royalty-free, non-exclusive license to use NIH-owned and patented background inventions only within the scope and term of the award. However, an SBIR offeror or SBIR contractor can apply for an exclusive or non-exclusive commercialization license to make, use, and sell products or services incorporating the NIH background invention. Offerors submitting an SBIR contract proposal in response to this topic are strongly encouraged to submit concurrently an application for a commercialization license to such background inventions. Under the NIH NCI TT program, the SBIR contract award process will be conducted in parallel with, but distinct from, the review of any applications for a commercialization license.

To apply for a commercialization license to develop this NIH invention, an SBIR offeror or SBIR contractor must submit a license application to the NIH Licensing and Patenting Manager: Sabarni Chatterjee, Ph.D., chatterjeesa@mail.nih.gov or 301-435-5587. Please visit http://www.ott.nih.gov/forms-model-agreements#LAP to get a pdf or word copy of the license application or to view model license agreements.

This license application provides NIH with information about the potential licensee, some of the terms desired, and the potential licensee's plans for development and/or commercialization of the invention. License applications will be treated in accordance with Federal patent licensing regulations as provided in 37 CFR Part 404. A further description of the NIH licensing process is available at http://www.ott.nih.gov/licensing-process. NIH will notify an SBIR offeror who has submitted an application for an exclusive commercialization license if another application for an exclusive license to the background invention is received at any time before such a license is granted.

Any invention developed by the contractor during the course of the NIH TT contract period of performance will be owned by the contractor subject to the terms of Section 8.5.

Topic 322 Real-Time Integration of Sensor and Self-Report Data for Clinical and Research Applications (Page 89), is revised to replace the link with the following:
http://www.healthit.gov/policy-researchers-implementers/meaningful-use-regulations

Section 9, SUBMISSION FORMS AND CERTIFICATIONS, is revised as follows to replace links:

9.1 Solicitation Attachments:

1. Proposal Intent Sheet: http://ncioa.cancer.gov/oa-internet/appl/rfp/BAA_N44CM47014-11/intent.pdf
   *Please complete and submit via E-mail to ncioasbir@mail.nih.gov no later than January 21, 2015.

2. Section K – Representations , Certifications, and other Statements:
   http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/sectionk_508.pdf

9.2 Technical Proposal Attachments:

3. SBIR Proposal Cover Sheet:
   http://grants.nih.gov/grants/funding/SBIRContract/ContractAppendixA.docx

6. Planned Enrollment Report, PHS-**398**/2590 (Rev. 08/12):
   http://grants.nih.gov/grants/funding/phs398/CumulativeInclusionEnrollmentReport.pdf

7. Technical Proposal Cost Summary:
   http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/Tech-Prop-Cost-Summ.pdf

8. Summary of Related Activities: http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/summary-related-activities.pdf

9.3 Business Proposal Attachments

13. NIH Form 2043, Proposal Summary and Data Record:
    http://www.grants.nih.gov/grants/funding/SBIRContract/ContractAppendixG.pdf

14. Breakdown of Proposed Estimated Costs (plus fee) w/excel spreadsheet: http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/spshexcl_dec2012.xlsx

15. Offeror's Points of Contact: http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/point-of-contact.pdf

16. Certificate of Current Cost or Pricing Data: http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/cert-current-cost.pdf

17. Small Business Certification Form is removed.

19. Adequate Accounting System Certification: http://ncioa.cancer.gov/oa-internet/appl/rfp/BAA_N44CM47014-11/AAS_Cert.pdf

9.4 Informational Attachments

22. Invoice/Financing Request and Contract Financial Reporting Instructions-Cost Reimbursement, NIH (RC)-4: http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/rc4_508.pdf

23. Safety and Health, HHSAR Clause 352.223-70: http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/Safety-Health-hhsar-1-06.pdf

24. Research Patient Care Costs, NIH(RC)-11: http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/rc11.pdf