



DATE

Our Reference:

Dear Business Official:

The above referenced pending application falls within the NIDDK zone of funding consideration and has been selected for a potential award. Any commitments and expenditures made prior to the receipt of the official Notice of Grant Award is at the grantees own risk. The information listed below must be provided in order for us to complete our review of this application and should be submitted in a timely manner to avoid delays in a potential award. All information should be approved by the Principal Investigator and an authorized institutional business official. You may transmit the information to us via email, fax or through the eRA NIH Commons (<https://commons.era.nih.gov/commons/>).

- Human Subjects Assurance - For applications involving human subjects, National Institutes of Health (NIH) policy requires prospective grantees to submit an assurance of compliance with protection of human subjects regulations. Since the research proposed in this application involves the use of human subjects, a Federal Wide Assurance (FWA) must be processed through DHHS's Office for Human Research Protections (OHRP) before an award can be issued. Instructions for applying for a FWA may be found at: <http://www.hhs.gov/ohrp/>
- Human Subjects Education Certification for Key Personnel - Before funds are awarded for competing applications or contract proposals involving human subjects, investigators must provide a description of education completed in the protection of human subjects for each individual identified as "key personnel" in the proposed research. Key personnel include all individuals responsible for the design and conduct of the study. Additional information on this requirement can be found in the NIH Guide Notice OD-00-039 at: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html>
- Investigators must submit a Data and Safety and Monitoring plan for phase I and II clinical trials to the funding Institute and Center (IC) before the trial begins. Please go to the following website for guidance: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-038.html>
- Animal Welfare Assurance - According to NIH policy, the NIH may support no activity involving animals until the prospective grantee conducting the activity has provided a written Assurance acceptable to NIH's Office for Laboratory Animal Welfare (OLAW). Since the research proposed in this application involves the use of animals, an Animal Welfare Assurance must be submitted to and accepted by OLAW before an award can be issued. We will contact OLAW and request that they contact you concerning the procedure for obtaining the appropriate assurance. Important information can be found at:

<http://grants.nih.gov/grants/olaw/olaw.htm>

- Animal Sharing Plan – If applicable, see NIH Model Organism Sharing Policy http://grants2.nih.gov/grants/policy/model_organism/
- EIN Number - Please provide the organization's Internal Revenue Service employer identification number (nine digits). If you do not have EIN number, please complete form W-9. See attached <http://www4.od.nih.gov/ofm/forms.html>
- Misconduct in Science Assurance – ORI also requires an annual report (PHS Form 6349) detailing aggregate information on allegations, inquiries and investigations that were handled by a grantee organization. The annual report constitutes the organizational official's assurance to ORI that the organization has established internal policies and procedures and will comply with PHS regulations for reviewing, investigating and reporting allegations of misconduct in science conducted at, or sponsored by, the organization.

To obtain the above-referenced form, or for additional information regarding scientific misconduct and research integrity, contact the Assurance Program, [Office of Research Integrity](http://ori.dhhs.gov/) (<http://ori.dhhs.gov/>).

- Total Cost Deviation - Routinely, SBIR and STTR Phase I awards do not exceed \$100,000 total costs (direct costs, indirect costs, and fee) and routinely, total costs for the entire proposed Phase II period do not exceed \$750,000 for SBIR and STTR projects. However, under special circumstances, applicants may propose greater amounts of funds necessary and appropriate for completion of the project. The ability to deviate from the statutory guidelines applies to NIH ONLY. Please provide a brief justification for the deviation. The justification should include all years that are applicable.
- Site Location - Whenever a proposed SBIR/STTR project is to be conducted in facilities other than those of the applicant organization, the small business concern should provide a letter from the organization stating that leasing/rental arrangements have been negotiated for appropriate research space. This letter should be submitted to us and signed by an authorized official of the organization whose facilities are to be used for the SBIR/STTR project. The letter must indicate that the small business concern (awardee organization) will have access to and control over the research space. In addition, the letter must include a description of the facilities and, if appropriate, equipment that will be leased/rented to the grantee organization.
- Updated Other Support Information - Please provide updated Other Support information for all key personnel. Information regarding the format of Other Support may be found at: http://grants.nih.gov/grants/funding/424/SF424_RR_Guide_SBIR_STTR.doc#_T

[oc116457986](#)

- The SBIR/STTR VERIFICATION STATEMENT contained in the SBIR/STTR Federal Financial and Business Management Systems Requirement must be received and accepted in this office before an award will be issued. You may furnish the information in a format of your choosing or by using the checklist provided. The Verification Statements may be found at:
http://grants.nih.gov/grants/funding/424/SF424_RR_Guide_SBIR_STTR.doc#_Toc116458009 or
<http://www.niddk.nih.gov/fund/crfo/ffbms/sbir-verification-statement.pdf>
<http://www.niddk.nih.gov/fund/crfo/ffbms/sttr-verification-statements.pdf>

All SBIR/STTR Grantees must have Federal Financial and Business Management Systems in place. Sample Policies and Procedures may be found at <http://www.niddk.nih.gov/fund/crfo/ffbms/>. To view documents in this format, you need a free copy of Adobe Acrobat Reader installed on your computer. If you do not have Adobe Acrobat Reader installed on your machine, feel free to download this free program from: <http://www.adobe.com/products/acrobat/readstep2.html>. Just clicking the link can access most web sites referenced throughout the document. Users need to be connected to the internet in order for clicked links to take them to the referenced site.

Please send the required information to my attention via e-mail at: **(your email address)** or by facsimile at: (301) 480-3504 or (301) 594-9523 no later than **(due date)**. If you have any questions, please call me at **(your phone number)**.

Sincerely,

YOUR NAME

Grants Management Specialist
National Institute for Diabetes and Digestive and Kidney Diseases

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The following information contains Internet websites that you may find useful:

- 1) <http://www.nih.gov/grants/funding/sbir.htm> - SBIR/STTR Home Page
- 2) <http://www.dpm.psc.gov> - Payment Management

Information regarding payment for grants awarded by NIH is available through the Division of Payment Management. The Program Support Center (PSC), DHHS, administers the Payment Management System. Inquiries regarding payments should be directed to:

Division of Payment Management

P.O. Box 6021
Rockville, MD 20852
(877) 614-5533

- 3) <http://www.nih.gov/grants/funding/welcomewagon.htm> - NIH “Welcome Wagon” Letter – New Grantees
Information provided in this memorandum is for officials of organizations receiving an award for the first time from the National Institutes of Health (NIH). The intent of this memorandum is to highlight key requirements, provide referrals to important sources of information available from NIH, and identify NIH and Department of Health and Human Services (HHS) offices having responsibility for certain administrative functions.
- 4) <http://www.hhs.gov/forms/publicuse.html> - HHS-690, Assurance of Compliance - New Grantees
Public policy requirements concerning civil rights, handicapped individuals, sex discrimination, and age discrimination require the one-time submission of Assurance Form HHS 690 prior to award and certification in all subsequent applications that the form (or the previous forms HHS 441, 641, 639-A, and 680) has been filed. The forms can be obtained at: <http://forms.psc.gov/forms/HHS/hhs.html>. Or send an email to grantsinfo@nih.gov mailto:grantsinfo@nih.gov - or call GRANTSINFO at (301) 435-0714. To inquire as to whether your organization has previously filed the HHS 690 or the previous forms, contact the DHHS Office of Civil Rights <http://www.hhs.gov/ocr> at (202) 619-0403.
- 5) <http://grants.nih.gov/grants/funding/sbirgrantsmanship.pdf> - Advice and Information on SBIR and STTR programs at the NIH
- 6) http://grants.nih.gov/grants/funding/sbir_policy.htm#audit - Clarification of Audit Reporting Requirements; <http://oamp.od.nih.gov/dfas/faqforprofitaudits.asp> – Audit FAQs
- 7) http://grants1.nih.gov/grants/policy/nihgps_2003/index.htm NIH Grants Policy Statement (12/03)