

## Attachment A

### Changes to the Supplemental Grant Application Instructions in 0925-0001

#### 1.7 Just-In-Time Policy

Several elements of an application are not required at the time the application is submitted. Instead, this information is requested later in the review cycle (i.e., “Just-in-Time”) to minimize burden to institutions and to ensure that the information is current. The information eligible for Just-in-Time submission includes:

- Current Other Support (not generally required for Fellowship applicants): See Part II Section 5.4 IRB Approval. See 1.8 [Other Support](#) policy information below. Use the sample format provided on the Other Support Format Page ([MS WORD](#) or [PDF](#)). For all senior/key personnel, provide details on adjustment of any budgetary, scientific, or effort overlap if the application is funded.

For Career Development Award applicants, information on all active support for the candidate, mentor(s), co-mentor(s), and senior/key personnel may be requested by the awarding component prior to award.

- Certifications:
  - If human subjects are involved, provide the Federalwide Assurance number (if not previously provided) and the Certification of IRB Review and Approval of the research proposed in the application, and any IRB imposed changes. Pending or out-of-date approvals cannot be accepted. IRB approval must be dated within the last year to be valid. See [Part II.5.4 IRB Approval](#).
  - If live vertebrate animals are involved, provide the Animal Welfare Assurance number of the applicant organization (if not previously provided), date of IACUC approval of the research proposed in the application, and any IACUC-imposed changes. Pending or out-of-date approvals cannot be accepted. IACUC approval must have been granted within three years to be valid. See [2.2 Vertebrate Animals](#).
  - For SBIR applicants, provide only upon request the SBIR Funding Agreement Certification noted in section 2.18. This should be submitted as an “Other Upload” file.
  - For STTR applicants, provide only upon request the STTR Funding Agreement Certification noted in section 2.19. This should be submitted as an “Other Upload” file.
  - For SBIR applicants that are majority-owned by multiple venture capital operating companies, hedge fund, or private equity firms, provide only upon request the SBIR Funding Agreement Certification (VCOCs) noted in section 2.20. This should be submitted as an “Other Upload” file.
- Human Embryonic Stem Cells (hESCs): If the proposed project involves hESCs and the applicant did not identify a hESC line from the NIH Human Embryonic Stem Cell Registry in the application, the line(s) may be submitted as an “Other Upload” file.
- Human Subjects Education: For applications that propose human subjects research, certification that each person identified as senior/key personnel involved in the design or conduct of research involving human subjects has completed an educational program in the protection of human subjects. See [Required Education in the Protection of Human Research Participants](#) in Part II, 5.5.
- Other Information Requested by the Awarding IC: Additional JIT information (i.e., revised budgets, changes to the human subjects, or vertebrate animal sections of the application) may be requested by NIH Institutes and/or Centers on a case-by-case basis. These should be submitted as an “Other Upload” file.

Applicants are advised to submit Just-in-Time information only when requested by the awarding component. Guidance for submitting this information will be provided at the time of the request. Alternatively, this information may be submitted using the Just-In-Time feature of the eRA Commons found in the **Status** section. For information on the Commons see: <https://commons.era.nih.gov/commons/index.jsp>.

NIH grant applicants are responsible for verifying the accuracy and validity of all information submitted through the Just-in-Time process and for promptly notifying NIH of any substantive changes to previously submitted Just-in-Time information up to the time of award.

### **1.18 Requirement for Individual Development Plans for Graduate Students and Postdoctoral Scientists**

In an effort to assist graduate students and post-doctorates achieve their developmental and career goals to become contributing members of the biomedical workforce, NIH requires grantees to develop an institutional policy requiring an Individual Development Plan (IDP) be implemented for every graduate student and post-doctorate supported by any NIH grant and reportable on the progress report, regardless of the type of NIH grant that is used for support. At this time, NIH does not expect grantees to submit copies of the actual IDPs, but does expect that the IDP plan be reported on in the progress report.

## 2.18 SBIR Funding Agreement Certification

Grant Application Number: \_\_\_\_\_

Organization: \_\_\_\_\_

Program Director(s)/Principal Investigator(s) (PD(s)/PI(s)): \_\_\_\_\_

All small businesses that are selected for award of an SBIR funding agreement must complete this certification at the time of award and any other time set forth in the Notice of Award that is prior to performance of work under this award. This includes checking all of the boxes and having an authorized officer of the awardee sign and date the certification each time it is requested.

Please read carefully the following certification statements. The Federal government relies on this information to determine whether the business is eligible for a Small Business Innovation Research (SBIR) Program award. A similar certification will be used to ensure continued compliance with specific program requirements during the life of the funding agreement. The definitions for the terms used in this certification are set forth in the Small Business Act, SBA regulations (13 C.F.R. Part 121), the SBIR Policy Directive and also any statutory and regulatory provisions references in those authorities.

If the Grants Management Officer believes that the business may not meet certain eligibility requirements at the time of award, they are required to file a size protest with the U.S. Small Business Administration (SBA), who will determine eligibility. At that time, SBA will request further clarification and supporting documentation in order to assist in the verification of any of the information provided as part of a protest. If the Grants Management Officer believes, after award, that the business is not meeting certain Notice of Award requirements, the agency may request further clarification and supporting documentation in order to assist in the verification of any of the information provided.

Even if correct information has been included in other materials submitted to the Federal government, any action taken with respect to this certification does not affect the Government's right to pursue criminal, civil, or administrative remedies for incorrect or incomplete information given in the certification. Each person signing this certification may be prosecuted if they have provided false information.

The undersigned has reviewed, verified and certifies that (all boxes must be checked):

1. The business concern meets the ownership and control requirements set forth in 13 C.F.R. § 121.702. Yes No
2. If a corporation, all corporate documents (articles of incorporation and any amendments, articles of conversion, by-laws and amendments, shareholder meeting minutes showing director elections, shareholder meeting minutes showing officer elections, organizational meeting minutes, all issued stock certificates, stock ledger, buy-sell agreements, stock transfer agreements, voting agreements, and documents relating to stock options, including the right to convert non-voting stock or debentures into voting stock) evidence that it meets the ownership and control requirements set forth in 13 C.F.R. § 121.702. Yes No N/A Explain why N/A
3. If a partnership, the partnership agreement evidences that it meets the ownership and control requirements set forth in 13 C.F.R. § 121.702. Yes No N/A Explain why N/A
4. If a limited liability company, the articles of organization and any amendments, and operating agreements and amendments, evidence that it meets the ownership and control requirements set forth in 13 C.F.R. § 121.702. Yes No N/A Explain why N/A
5. The birth certificates, naturalization papers, or passports show that any individuals it relies upon to meet the eligibility requirements are U.S. citizens or permanent resident aliens in the United States. Yes No N/A Explain why N/A
6. It has no more than 500 employees, including the employees of its affiliates. Yes No
7. SBA has not issued a size determination currently in effect finding that this business concern exceeds the 500 employee size standard. Yes No
8. During the performance of the award, the principal investigator will spend more than half of his/her time as an employee of the awardee or has requested and received a written deviation from this requirement from the Grants Management Officer. Yes No Deviation approved in writing by Grants Management Officer: \_\_\_\_%
9. All, essentially equivalent work, or a portion of the work proposed under this project (check the applicable line):
  - Has not been submitted for funding by another Federal agency
  - Has been submitted for funding by another Federal agency but has not been funded under any other Federal grant, contract, subcontract, or other transaction.

A portion has been funded by another grant, contract, or subcontract as described in detail in the proposal and approved in writing by the Grants Management Officer.

10. During the performance of award, it will perform the applicable percentage of work unless a deviation from this requirement is approved in writing by the Grants Management Officer (check the applicable line and fill in if needed):

SBIR Phase I: at least two-thirds (66 2/3%) of the research

SBIR Phase II: at least half (50%) of the research

Deviation approved in writing by the Grants Management Officer: %

11. During performance of award, the research/research and development will be performed in the United States unless a deviation is approved in writing by the Grants Management Officer.
12. During the performance of award, the research/research and development will be performed at my facilities with my employees, except as otherwise indicated in the SBIR application and approved in the Notice of Award. Yes No
13. It has registered itself on SBA's database as majority-owned by venture capital operating companies, hedge funds or private equity firms. Yes No N/A Explain why N/A
14. It is a Covered Small Business Concern (a small business concern that: (a) was not majority-owned by multiple venture capital operating companies (VCOCs), hedge funds, or private equity firms on the data on which it submitted an application in response to an SBIR solicitation; and (b) on the date of the SBIR award, which is made more than 9 months after the closing date of the solicitation, is majority-owned by multiple venture capital operating companies, hedge funds, or private equity firms). Yes No

It will notify the Federal agency immediately if all or a portion of the work proposed is subsequently funded by another Federal agency.

I understand that the information submitted may be given to Federal, State and local agencies for determining violations of law and other purposes.

I am an officer of the business concern authorized to represent it and sign this certification on its behalf. By signing this certification, I am representing on my own behalf, and on behalf of the business concern that the information provided in this certification, the application, and all other information submitted in connection with this application, is true and correct as of the date of submission. I acknowledge that any intentional or negligent misrepresentation of the information contained in this certification may result in criminal, civil or administrative sanctions, including but not limited to: (1) fines, restitution and/or imprisonment under 18 U.S.C. § 1001; (2) treble damages and civil penalties under the False Claims Act (31 U.S.C. § 3729 et seq); (3) double damages and civil penalties under the Program Fraud Civil Remedies Act (31 U.S.C. §3801 et seq); (4) civil recovery of award funds; (5) suspension and/or debarment from all Federal procurement and nonprocurement transactions (FAR Subpart 9.4 or 2 C.F.R. part 180; and (6) other administrative penalties including termination of SBIR/STTR awards.

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(Official Authorized to Sign for the Organization)

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(Date)

## 2.19 STTR Funding Agreement Certification

Grant Application Number: \_\_\_\_\_

Organization: \_\_\_\_\_

Program Director(s)/Principal Investigator(s) (PD(s)/PI(s)): \_\_\_\_\_

All small businesses that are selected for award of an STTR funding agreement must complete this certification at the time of award and any other time set forth in the Notice of Award that is prior to performance of work under this award. This includes checking all of the boxes and having an authorized officer of the awardee sign and date the certification each time it is requested.

Please read carefully the following certification statements. The Federal government relies on this information to determine whether the business is eligible for a Small Business Technology Transfer (STTR) Program award. A similar certification will be used to ensure continued compliance with specific program requirements during the life of the funding agreement. The definitions for the terms used in this certification are set forth in the Small Business Act, SBA regulations (13 C.F.R. Part 121), the SBIR Policy Directive and also any statutory and regulatory provisions references in those authorities.

If the Grants Management Officer believes that the business may not meet certain eligibility requirements at the time of award, they are required to file a size protest with the U.S. Small Business Administration (SBA), who will determine eligibility. At that time, SBA will request further clarification and supporting documentation in order to assist in the verification of any of the information provided as part of a protest. If the Grants Management Officer believes, after award, that the business is not meeting certain funding agreement requirements, the agency may request further clarification and supporting documentation in order to assist in the verification of any of the information provided.

Even if correct information has been included in other materials submitted to the Federal government, any action taken with respect to this certification does not affect the Government's right to pursue criminal, civil, or administrative remedies for incorrect or incomplete information given in the certification. Each person signing this certification may be prosecuted if they have provided false information.

The undersigned has reviewed, verified and certifies that (all boxes must be checked):

1. The business concern meets the ownership and control requirements set forth in 13 C.F.R. § 121.702. Yes No
2. If a corporation, all corporate documents (articles of incorporation and any amendments, articles of conversion, by-laws and amendments, shareholder meeting minutes showing director elections, shareholder meeting minutes showing officer elections, organizational meeting minutes, all issued stock certificates, stock ledger, buy-sell agreements, stock transfer agreements, voting agreements, and documents relating to stock options, including the right to convert non-voting stock or debentures into voting stock) evidence that it meets the ownership and control requirements set forth in 13 C.F.R. § 121.702. Yes No N/A Explain why N/A
3. If a partnership, the partnership agreement evidences that it meets the ownership and control requirements set forth in 13 C.F.R. § 121.702. Yes No N/A Explain why N/A
4. If a limited liability company, the articles of organization and any amendments, and operating agreements and amendments, evidence that it meets the ownership and control requirements set forth in 13 C.F.R. § 121.702. Yes No N/A Explain why N/A
5. The birth certificates, naturalization papers, or passports show that any individuals it relies upon to meet the eligibility requirements are U.S. citizens or permanent resident aliens in the United States. Yes No N/A Explain why N/A
6. It has no more than 500 employees, including the employees of its affiliates. Yes No
7. SBA has not issued a size determination currently in effect finding that this business concern exceeds the 500 employee size standard. Yes No
8. During the performance of the award, the principal investigator will spend more than half of his/her time as an employee of the awardee or has requested and received a written deviation from this requirement from the Grants Management Officer. Yes No Deviation approved in writing by Grants Management Officer: \_\_\_\_%
9. All, essentially equivalent work, or a portion of the work proposed under this project (check the applicable line):
  - Has not been submitted for funding by another Federal agency
  - Has been submitted for funding by another Federal agency but has not been funded under any other Federal grant, contract, subcontract, or other transaction.

A portion has been funded by another grant, contract, or subcontract as described in detail in the proposal and approved in writing by the Grants Management Officer.

10. During the performance of award, it will perform the applicable percentage of work unless a deviation from this requirement is approved in writing by the Grants Management Officer (check the applicable line and fill in if needed):

STTR Phase I: at least forty (40%) of the research

STTR Phase II: at least forty (40%) of the research

Deviation approved in writing by the Grants Management Officer: %

11. During performance of award, the research/research and development will be performed in the United States unless a deviation is approved in writing by the Grants Management Officer.
12. During the performance of award, the research/research and development will be performed at my facilities with my employees, except as otherwise indicated in the STTR application and approved in the Notice of Award. Yes No
13. It has registered itself on SBA's database as majority-owned by venture capital operating companies, hedge funds or private equity firms. Yes No N/A Explain why N/A
14. The small business concern has provided satisfactory evidence that it will exercise management direction and control of the performance of the STTR funding agreement. Yes No

It will notify the Federal agency immediately if all or a portion of the work proposed is subsequently funded by another Federal agency.

I understand that the information submitted may be given to Federal, State and local agencies for determining violations of law and other purposes.

I am an officer of the business concern authorized to represent it and sign this certification on its behalf. By signing this certification, I am representing on my own behalf, and on behalf of the business concern, that the information provided in this certification, the application, and all other information submitted in connection with this application, is true and correct as of the date of submission. I acknowledge that any intentional or negligent misrepresentation of the information contained in this certification may result in criminal, civil or administrative sanctions, including but not limited to: (1) fines, restitution and/or imprisonment under 18 U.S.C. § 1001; (2) treble damages and civil penalties under the False Claims Act (31 U.S.C. § 3729 et seq); (3) double damages and civil penalties under the Program Fraud Civil Remedies Act (31 U.S.C. §3801 et seq); (4) civil recovery of award funds; (5) suspension and/or debarment from all Federal procurement and nonprocurement transactions (FAR Subpart 9.4 or 2 C.F.R. part 180; and (6) other administrative penalties including termination of SBIR/STTR awards.

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(Official Authorized to Sign for the Organization)

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(Date)

## 2.20 SBIR Funding Agreement Certification (VCOCs)

### NIH SMALL BUSINESS INNOVATION RESEARCH PROGRAM

#### CERTIFICATION FOR APPLICANTS THAT ARE MAJORITY-OWNED BY MULTIPLE VENTURE CAPITAL OPERATING COMPANIES, HEDGE FUND, OR PRIVATE EQUITY FIRMS

Grant Application Number: \_\_\_\_\_

Organization: \_\_\_\_\_

Project Director(s)/Principal Investigator(s)

(PD(s)/PI(s): \_\_\_\_\_

Any small businesses that are majority-owned by multiple venture operating companies (VCOCs), hedge funds or private equity firms and are submitting an application for an SBIR funding agreement must complete this certification prior to submitting an application. This includes checking all of the boxes and having an authorized officer of the applicant organization sign and date the certification each time it is requested.

Please read carefully the following certification statements. The Federal government relies on the information to determine whether the business is eligible for a Small Business Innovation Research (SBIR) Program award and meets the specific program requirements during the life of the funding agreement. The definitions for the terms used in this certification are set forth in the Small Business Act, SBA regulations (13 C.F.R. Part 121), the SBIR Policy Directive and also any statutory and regulatory provisions referenced in those authorities.

If the funding agreement officer believes that the business may not meet certain eligibility requirements at the time of award, they are required to file a size protest with the U.S. Small Business Administration (SBA), who will determine eligibility. At that time, SBA will request further clarification and supporting documentation in order to assist in the verification of any of the information provided as part of a protest. If the funding agreement officer believes, after award, that the business is not meeting certain funding agreement requirements, the agency may request further clarification and supporting documentation in order to assist in the verification of any of the information provided.

Even if correct information has been included in other materials submitted to the Federal government, any action taken with respect to this certification does not affect the Government's right to pursue criminal, civil or administrative remedies for incorrect or incomplete information given in the certification. Each person signing this certification may be prosecuted if they have provided false information.

The undersigned has reviewed, verified and certifies that (all boxes must be checked):

1. The applicant is NOT more than 50% owned by a single VCOC, hedge fund or private equity firm.

Yes  No

2. The applicant is more than 50% owned by multiple domestic business concerns that are VCOCs, hedge funds, or private equity firms.

Yes  No

3. I have registered with SBA at [www.SBIR.gov](http://www.SBIR.gov) as a business that is majority-owned by multiple VCOCs, hedge funds or private equity firms.

Yes  No

I understand that the information submitted may be given to Federal, State and local agencies for determining violations of law and other purposes.

All the statements and information provided in this form and any documents submitted are true, accurate and complete. If assistance was obtained in completing this form and the supporting documentation, I have personally reviewed the information and it is true and accurate. I understand that, in general, these statements are made for the purpose of determining eligibility for an SBIR funding agreement and continuing eligibility.

I understand that the certifications in this document are continuing in nature. Each SBIR funding agreement for which the small business submits an offer or application or receives an award constitutes a restatement and reaffirmation of these certifications.

I understand that I may not misrepresent status as small business to: 1) obtain a contract under the Small Business Act; or 2) obtain any benefit under a provision of Federal law that references the SBIR Program.

I am an officer of the business concern authorized to represent it and sign this certification on its behalf. By signing this certification, I am representing on my own behalf, and on behalf of the SBIR applicant or awardee, that the information provided in this certification, the application, and all other information submitted in connection with this application, is true and correct as of the date of submission. I acknowledge that any intentional or negligent misrepresentation of the information contained in this certification may result in criminal, civil or administrative sanctions, including but not limited to:

- (1) fines, restitution and/or imprisonment under 18 U.S.C. §1001;
- (2) treble damages and civil penalties under the False Claims Act (31 U.S.C. §3729 *et seq.*);
- (3) double damages and civil penalties under the Program Fraud Civil Remedies Act (31 U.S.C. §3801 *et seq.*);
- (4) civil recovery of award funds,
- (5) suspension and/or debarment from all Federal procurement and nonprocurement transactions (FAR Subpart 9.4 or 2 C.F.R. part 180); and
- (6) other administrative penalties including termination of SBIR/STTR awards.

My signature is verification that the statements checked ( ) above are true and complete. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

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(Official Authorized to Sign for the Organization)

(Date)

## 5.2. Terms and Conditions of Award

**Life Cycle Certification:** All SBIR and STTR awardees must complete a life cycle certification at all times set forth in the Notice of Award. Awardees are not required to submit this certification directly to the NIH but must complete and maintain it on file in accordance with the records retention policy in NIH Grants Policy Statement Section 8.4.2. A certification is required at the following times:

- For SBIR & STTR Phase I Awardees: At the time of receiving final payment or disbursement from the Payment Management System
- For SBIR & STTR Phase II Awardees: prior to receiving more than 50% of the total award amount and prior to final payment or disbursement from the Payment Management System.

In addition, SBIR/STTR awardees indicate compliance with these certification requirements by drawing or requesting funds from the Payment Management System. If the grantee cannot complete this certification or cannot ensure compliance with the certification process, it should notify the GMO immediately upon. If resolution cannot be reached, the GMO will void the grant. For additional information on this requirement, SBIR grantees should refer to NIH Grants Policy Statement Section 18.5.5.4; STTR grantees should refer to section 18.5.5.5.

**Pre-award Costs.** A potential grantee may, *at its own risk* and without NIH prior approval, incur obligations and expenditures to cover costs up to 90 days prior to the effective date of a new or competing continuation award if such costs:

- Are necessary to conduct the project, and
- Would be allowable under the grant, if awarded, without NIH prior approval.

Upon acceptance of a grant award, the grantee must comply with the terms and conditions contained or referenced in the Notice of Award document. These terms and conditions, constituting legal requirements imposed on an awardee by statute, regulations, administrative policy, or the award document itself, are either “standard” or “special” as follows:

**Standard Terms and Conditions.** Those that are required by policy to be incorporated by reference in Notices of Grant Award through citations of specific documents that contain requirements applicable to the grant.

**Special Terms and Conditions.** Those that are judged necessary to attain the objectives for which the grant is being awarded, facilitate post-award administration, conserve grant funds, or otherwise protect the interests of the Federal Government. They are stated in full on the Notice of Award.

**NIH Standard Terms of Award.** Under NIH Standard Terms of Award, the grantee organization may elect to extend the project period for up to 12 months without additional funds. At least 10 days prior to the original project end date, the grantee must *notify* the awarding agency Grants Management Official (GMO) in writing (e-mail or letter) of the extension. The notification must be signed by the authorizing business official and must include the new project end date. Extensions beyond the initial notification must be *requested* by the grantee organization and *approved* by the awarding GMO.

Grant awards must be administered in accordance with the *NIH Grants Policy Statement* ([http://grants.nih.gov/grants/policy/nihgps\\_2012/index.htm](http://grants.nih.gov/grants/policy/nihgps_2012/index.htm)) including the Public Policy Requirements outlined in Chapter 4 and requirements specific to For-Profit Institutions outlined in Chapter 18.