

entities implement the requirement for limited review of research by an IRB to meet the conditions of four exemptions found at 45 CFR 46.104(d) of the 2018 Requirements (the Common Rule). The draft guidance discusses the concept of limited IRB review, which appears in these exemptions, and provides information about how limited review may be conducted. When finalized, this will provide OHRP's first formal guidance on this topic. This draft guidance was developed after taking into consideration input received from HHS and other Common Rule departments and agencies.

II. Equity and Justice Considerations

OHRP is particularly interested in public comments on any impact this guidance may have on considerations for equity and justice in human research protections.

III. Electronic Access

Persons with access may obtain the draft guidance documents on OHRP's website at <https://www.hhs.gov/ohrp/regulations-and-policy/requests-for-comments/index.html>.

Julie A. Kaneshiro,

Acting Director, Office for Human Research Protections.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Implementation of the NIH SBIR and STTR Foreign Disclosure Pre-Award and Post-Award Requirements

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Institutes of Health (NIH) announces publication and serves as Notice for the extramural community on recent policy changes made for the Small Business Innovation Research Program (SBIR) and the Small Business Technology Transfer Program (STTR). This Notice implements additional disclosure requirements and post-award reporting requirements for small business concerns (SBCs) for covered relationships. In addition, this serves as notification of NIH's due diligence program to assess security risks and denial of award when foreign relationships or commitments with countries of concern pose a significant risk as provided in the SBIR and STTR Extension Act of 2022 at <https://>

www.congress.gov/117/plaws/publ183/PLAW-117publ183.pdf under these programs. This policy serves as an update to section 18. Grants to For Profit Organizations of the NIH Grants Policy Statement (GPS) at https://grants.nih.gov/grants/policy/nihgps/HTML5/section_18/18_grants_to_for-profit_organizations.htm and will be incorporated in the FY24 publication. In addition, the NIH Application Guide will be updated to reflect instructions for submission of required documentation.

DATES: The policy changes are now available for viewing.

ADDRESSES: Please visit our website to view the policy changes at <https://grants.nih.gov/policy/PolicyNotices.php>.

FOR FURTHER INFORMATION CONTACT: Stephanie Fertig, Health and Human Services (HHS) Small Business Program Lead, Small business Education and Entrepreneurial Development (SEED). Email: SEEDinfo@nih.gov. Phone number (301) 827-8595. Centers for Disease Control and Prevention (CDC) Contact: Terrance Perry, CDC Office of Grants Services, Office of Financial Resources. Email: OGSPolicy@cdc.gov. Phone number (770) 488-8424). Food and Drug Administration (FDA) Contact: Kimberly Pendleton, FDA Office of Finance, Budget, Acquisitions, and Planning. Email: Kimberly.Pendleton@fda.hhs.gov. Phone number (240) 402-7610.

SUPPLEMENTARY INFORMATION:

Background

The SBIR and STTR Extension Act of 2022 (the Act) Public Law 117-183, 136 stat. 2180 <https://www.congress.gov/117/plaws/publ183/PLAW-117publ183.pdf>, signed into law by President Biden on September 30, 2022, reauthorized the SBIR program, the STTR program, and related pilot programs through September 30, 2025.

The Act includes major changes to the SBIR and STTR programs, including:

- increased minimum performance standards (refer to *NOT-OD-23-092*, <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-23-092.html>),
- disclosure requirements regarding ties to foreign countries,
- a requirement for federal agencies that manage SBIR and STTR programs to establish a due diligence program to assess security risks posed by applicants,
- denial of award and recovery authority provisions when ties to foreign countries of concern pose a significant risk.

Foreign countries of concern are defined in the Act as the People's Republic of China, the Democratic People's Republic of North Korea, the Russian Federation, the Islamic Republic of Iran, or any other country determined to be a country of concern by the U.S. Secretary of State. An up-to-date list of countries determined to be countries of concern by the Secretary of State will be maintained and accessible on [SBIR.gov](https://www.sbir.gov/foreign_disclosures) on SBA's Required Disclosures of Foreign Affiliations or Relations web page at https://www.sbir.gov/foreign_disclosures.

In response to the passing of the Act, the U.S. Small Business Administration (SBA) has issued a form, *Required Disclosures of Foreign Affiliations or Relationships to Foreign Countries* (referred to as the "disclosure form" hereafter) that will be administered by federal agencies to identify and assess the risk of covered foreign relationships for SBC applicants applying for SBIR and STTR funding. Publication of the final form is forthcoming.

Applicability

This policy applies to all competing applications for funding under the NIH, CDC, and FDA SBIR and STTR programs submitted for due dates on or after September 5, 2023.

Policy

Each SBC applying for the SBIR and STTR programs under the NIH, CDC, and FDA is required to disclose all funded and unfunded relationships with foreign countries, using the disclosure form, for all owners and covered individuals. A "covered individual" is defined as all senior key personnel identified by the SBC in the application (*i.e.*, individuals who contribute to the scientific development or execution of a project in a substantive, measurable way). Applicants must include the following information on the disclosure form:

- the identity of all owners and covered individuals of the SBC who are a party to any malign foreign talent recruitment program;
- the existence of any parent company, joint venture, or subsidiary of the SBC that is based in or receives funding from, any foreign country of concern;
- any current or pending contractual or financial obligation or other agreement specific to a business arrangement, or joint venture-like arrangement with an enterprise owned by a foreign state or any foreign entity;
- whether the SBC is wholly owned in a foreign country;

- any venture capital or institutional investment and if the investing entity has a general partner or any other individual holding a leadership who has a foreign affiliation with any foreign country of concern;

- any technology licensing or intellectual property sales or transfers to a foreign country of concern during the 5-year period preceding submission of the proposal;

- any foreign business entity, offshore entity, or entity outside the United States related to the SBC;

- any owners, officers, or covered individuals that have a foreign affiliation with a research institution located in a foreign country of concern;

- information technology and information safeguarding plans.

Upon request, applicants will submit the completed disclosure form via the Just-In-Time (JIT) process described in the NIH GPS section 2.5.1 Just-in-Time Procedures at https://grants.nih.gov/grants/policy/nihgps/HTML5/section_2/2.5.1_just-in-time_procedures.htm. The disclosure form and any additional agency-specific information must be submitted electronically using the Just-in-Time feature in the eRA Commons. Applicants must continue to comply with NIH Other Support disclosure requirements as provided in Section 2.5.1 at https://grants.nih.gov/grants/policy/nihgps/HTML5/section_2/2.5.1_just-in-time_procedures.htm. SBC applicants applying to CDC and FDA will follow each agency's policies for submitting additional documents during the pre-award process. Applicants may be required to provide similar information on the disclosure form that is also submitted as a part of the other support reporting for senior/key personnel identified in the application. Applicants that do not submit the completed disclosure form during the JIT process will not be considered for funding.

SBIR/STTR Notices of funding opportunities and terms and conditions of award will be updated to reflect the policy above.

Due Diligence Program To Assess Security Risks

NIH, CDC, and FDA have implemented a due diligence program designed to assess security risks posed by applicants. The due diligence program will assess the cybersecurity practices, patent analysis, employee analysis, and foreign ownership of a SBC seeking an award, including the financial ties and obligations of the SBC and employees of the SBC to a foreign country, foreign person, or foreign entity. After reviewing the application,

including JIT elements and the disclosure form, NIH, CDC, and FDA may request the SBC provide copies of any contractual or financial obligation or other agreement specific to a business arrangement, or joint venture-like arrangement with an enterprise owned by a foreign state or any foreign entity in effect during the 5-year period (calendar year) preceding submission of the proposal. NIH, CDC, and FDA may decline to move forward with an award based on security risks determined during the assessment. NIH, CDC, and FDA will not issue an award prior to completing the assessment process.

Denial of Awards

Applicants and recipients are encouraged to consider whether their entity's relationships with foreign countries of concern will pose a security risk. Prior to issuing an award, NIH, CDC, and FDA will determine whether the SBC submitting the application:

- has an owner or covered individual that is party to a malign foreign talent recruitment program;
- has a business entity, parent company, or subsidiary located in the People's Republic of China or another foreign country of concern; or
- has an owner or covered individual that has a foreign affiliation with a research institution located in the People's Republic of China or another foreign country of concern.

A finding of foreign involvement with countries of concern will not necessarily disqualify an applicant. NIH, CDC, and FDA will provide SBC applicants the opportunity to address any identified security risks prior to award. Final award determinations will be based on whether the applicant's involvement falls within any of the following risk criteria, per the Act:

- interfere with the capacity for activities supported by NIH, CDC, or FDA to be carried out;
- create duplication with activities supported by NIH, CDC, or FDA;
- present concerns about conflicts of interest;
- were not appropriately disclosed to NIH, CDC, or FDA;
- violate Federal law or terms and conditions of NIH, CDC, or FDA; or
- pose a risk to national security.

NIH, CDC, and FDA will not issue an award under the SBIR/STTR program if the covered relationship with a foreign country of concern identified in this guidance is determined to fall under any of the criteria provided above, and the risk cannot be resolved.

Post-Award Reporting Requirements

Recipients are responsible for monitoring their relationships with

foreign countries of concern post-award, for any changes that may impact previous disclosures. SBCs receiving an award under the SBIR/STTR program are required to submit an updated disclosure form to report any of the following changes to NIH, CDC, and FDA throughout the duration of the award:

- any change to a disclosure on the disclosure form;
- any material misstatement that poses a risk to national security; and
- any change of ownership, change to entity structure, or other substantial change in circumstances of the SBC that NIH, CDC, and FDA determine poses a risk to national security.

Updated disclosure forms are required within 30 days of any change in ownership, entity structure, covered individual, or other substantive changes in circumstance, as described above. In addition, regular updates are required at the time of all SBIR/STTR annual, interim, and final Research Performance Progress Reports (RPPRs). Recipients will be required to upload these updated disclosures using the Additional Materials (AM) tool in eRA Commons. System enhancements to facilitate these uploads are underway, with an anticipated deployment in calendar year 2024. The RPPR Instruction Guide will be updated to reflect this process.

If the recipient reports a covered foreign relationship that meets any of the risk criteria prohibiting funding described in this guidance, NIH, CDC, and FDA may withhold funding until the covered relationship has been dissolved. The recipient will be required to submit documentation verifying the relationship has been terminated. If the risk cannot be resolved, NIH, CDC, and FDA may deem it necessary to terminate the award for material failure to comply with the federal statutes, regulations, or terms and conditions of the federal award. Refer to Section 8.5.2 Remedies for Noncompliance or Enforcement Actions: Suspension, Termination, and Withholding of Support (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_8/8.5.2_remedies_for_noncompliance_or_enforcement_actions-suspension_termination_and_withholding_of_support.htm?Highlight=termination for more information. Recipients are encouraged to monitor their covered foreign relationships post-award and avoid entering into relationships, both funded and unfunded, that may pose a security risk and jeopardize their ability to retain their award.

Agency Recovery Authority and Repayment of Funds

An SBC will be required to repay all amounts received from NIH, CDC, and FDA under the award if either of the following determinations are made upon assessment of a change to their disclosure:

- the SBC makes a material misstatement that NIH, CDC, and FDA determine poses a risk to national security; or
- there is a change in ownership, change in entity structure, or other substantial change in circumstances of the SBC that NIH, CDC, and FDA determine poses a risk to national security.

The repayment requirements and procedures provided in Section 8.5.4 Recovery of Funds at https://grants.nih.gov/grants/policy/nihgps/HTML5/section_8/8.5.4_recovery_of_funds.htm of the NIH GPS apply and may also be subject to additional noncompliance and enforcement actions as described in Section 8.5.2 of the GPS. Recipients are required to follow the repayment procedures provided in the Guidance for Repayment of Grant Funds to the NIH at <https://grants.nih.gov/policy/compliance.htm>.

Dated: June 6, 2023.

Tara A. Schwetz,

Acting Principal Deputy Director, National Institutes of Health.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Therapeutic Immune Regulation.

Date: July 13–14, 2023.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, 1 Bethesda Metro Center, Bethesda, MD 20814.

Contact Person: Yue Wu, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 803C, Bethesda, MD 20892, (301) 867-5309, wuy25@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fellowships: Behavioral Neuroscience.

Date: July 13–14, 2023.

Time: 8:30 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Garden Inn, Washington DC/Georgetown, 2201 M Street NW, Washington, DC 20037.

Contact Person: Simone Chebabo Weiner, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1011K, Bethesda, MD 20892, (301) 435-1042, weinersc@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fellowships: Cancer Immunology and Immunotherapy.

Date: July 13–14, 2023.

Time: 9:30 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Ola Mae Zack Howard, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4192, MSC 7806, Bethesda, MD 20892, 301-451-4467, howardz@mail.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fellowships: Cell Biology, Developmental Biology, and Bioengineering.

Date: July 13–14, 2023.

Time: 9:30 a.m. to 7:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Alexander Gubin, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4196, MSC 7812, Bethesda, MD 20892, 301-435-2902, gubina@csr.nih.gov.

Name of Committee: Infectious Diseases and Immunology B Integrated Review Group; HIV Immunopathogenesis and Vaccine Development Study Section.

Date: July 13–14, 2023.

Time: 10:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Shiv A. Prasad, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5220,

MSC 7852, Bethesda, MD 20892, 301-443-5779, prasads@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Health Services and Systems.

Date: July 13, 2023.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Wenjuan Wang, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institute of Health, 6701 Rockledge Drive, Room 3154, Bethesda, MD 20892, (301) 480-8667, wangw22@mail.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Bioengineering, Surgery, Anesthesiology, and Trauma.

Date: July 13, 2023.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Donald Scott Wright, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5108, MSC 7854, Bethesda, MD 20892, (301) 435-8363, wrightds@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Topics in Pathogenic Eukaryotes.

Date: July 13, 2023.

Time: 10:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Bakary Drammeh, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 805-P, Bethesda, MD 20892, (301) 435-0000, drammehbs@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Topics in Aging.

Date: July 13, 2023.

Time: 11:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Thomas Y Cho, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 710B, Bethesda, MD 20892, (301) 402-4179, thomas.cho@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Skeletal Muscle and Exercise Physiology/Musculoskeletal Rehabilitation Sciences.

Date: July 13, 2023.

Time: 11:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.