

Funding is awarded through the Epidemiology and Laboratory cooperative agreements (ELC), and is intended to provide critical resources to recipients in support of a broad range of healthcare infection prevention and control and epidemiologic surveillance activities to detect, monitor, mitigate, and prevent the spread of HAI/AR in healthcare settings.

HAI/AR programs have experienced an increase in program size and scope

through COVID-19 supplemental funds. To better support the growing programs, CDC has developed high-priority trainings requested by the health department programs with the goal of strengthening public health workforce capacity to prevent and respond to HAI/AR outbreaks in healthcare settings, including preventing the spread of SARS-CoV-2. The proposed training evaluation will be used to assess whether the CDC-developed trainings

are reaching the intended audience and achieving the intended goal of strengthening public health workforce capacity to prevent and respond to HAI/AR outbreaks, including COVID-19, at the individual trainee and program level.

CDC requests OMB approval for an estimated 316 annual burden hours. There is no cost to respondents other than their time to participate.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
Public Health Trainees	Registration	600	2	5/60	100
Public Health Trainees	Pre-test	600	2	5/60	100
Public Health Trainees	Post-test	600	2	5/60	100
HAI/AR Program Leads	Public Health program impact of trainings ...	64	1	15/60	16
Total					316

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Public Health Ethics and Regulations, Office of Science, Centers for Disease Control and Prevention.

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BILLING CODE 4163-18-P

Dated: June 13, 2023.

Xavier Becerra, Secretary.

[FR Doc. 2023-12983 Filed 6-15-23; 8:45 am]

BILLING CODE 4154-01-P

Office for Human Research Protections, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852.

Instructions: All submissions received must include the docket number. All comments received, including attachments and any personal information, will be posted without change to <https://www.regulations.gov>.

Submit written requests for a single copy of the guidance document titled, "Frequently Asked Questions: Limited Institutional Review Board Review and Related Exemptions" to the Division of Policy and Assurances, Office for Human Research Protections, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852. Send one self-addressed adhesive label to assist that office in processing your request or fax your request to 240-453-8420. See the

SUPPLEMENTARY INFORMATION section for information on access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Natalie Klein, Ph.D., Office for Human Research Protections, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852, 240-453-6700; email natalie.klein@hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

OHRP is announcing the availability of a draft guidance document for public comment titled "Frequently Asked Questions: Limited Institutional Review Board Review and Related Exemptions." The draft guidance document applies to research activities involving human subjects that are conducted or supported by HHS. It is intended primarily to help

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living
Statement of Delegation of Authority

I hereby delegate to the individual serving as the Administrator and Assistant Secretary for Aging for the Administration for Community Living the authority to oversee and administer the operations of the Interagency Coordinating Committee on Healthy Aging and Age-Friendly Communities as outlined in section 203(c) Older Americans Act of 1965 (Pub. L. 89-73, as amended through Pub. L. 116-131, enacted March 25, 2020).

This delegation excludes the authority to issue regulations and shall be exercised in accordance with the Department's applicable policies, procedures, and guidance. This authority may be redelegated.

This delegation of authority is effective immediately upon signature. I hereby affirm and ratify any actions taken by you or your subordinates that involved the exercise of the authorities delegated herein prior to the effective date of the delegation.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Docket No. HHS-OASH-2022-0014]

Draft Guidance on Frequently Asked Questions: Limited Institutional Review Board Review and Related Exemptions

AGENCY: The Office for Human Research Protections, Office of the Assistant Secretary for Health, Office of the Secretary, HHS.

ACTION: Notice of availability.

SUMMARY: The Office for Human Research Protections (OHRP), Office of the Assistant Secretary for Health, is announcing the availability of a draft guidance document titled, "Frequently Asked Questions: Limited Institutional Review Board Review and Related Exemptions."

DATES: Submit written comments by August 15, 2023.

ADDRESSES: You may send comments, identified by docket number HHS-OASH-2022-0014, by any of the following methods:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments.
- Email: OHRP@hhs.gov.
- Fax: 240-453-8420.
- Mail/Hand Delivery/Courier: Division of Policy and Assurances,

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) 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;