Workplan Templates for Self-Attestation Statement Template for the Framework for Nucleic Acid Synthesis Screening

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Supporting Statement A

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ATTACHMENTS

JUSTIFICATION SUMMARY

Goal of the project: The goal of the project is to assist providers and manufacturers of synthetic nucleic acids and benchtop nucleic acid synthesis equipment (providers) in making an attestation that they have instituted a process to screen nucleic acid sequences of concern and verify customer legitimacy, in accordance with the requirements outlaid in the OSTP Framework for Nucleic Acid Synthesis Screening (Attachment 1).

Intended use of the resulting data: Under the Framework for Nucleic Acid Synthesis Screening, providers are directed to either post the statement on their website or share it with the funding agency and customer upon request to demonstrate compliance with federal funding requirements.

Methods to be used to collect: A self-attestation form will be shared publicly that providers may use to attest to compliance. They may then share this form with federal funders when selling synthetic nucleic acids to federal agencies or federally funded researchers, and/or post on their websites. This form is intended to be completed annually.

The subpopulation to be studied: Providers and manufacturers of synthetic nucleic acids and bench top nucleic acid synthesis equipment.

How data will be analyzed: There is no plan to use statistical methods or other analytic techniques on the data. It is purely to demonstrate compliance with upcoming federal funding conditions.

A. JUSTIFICATION

A1. Circumstances Making the Collection of Information Necessary

This form was developed pursuant to the Framework for Nucleic Acid Synthesis Screening (Attachment 1), which was released by the Office of Science and Technology Policy (OSTP) in April of 2024. This framework was directed by the *Executive Order on the Safe, Secure, and Trustworthy Development of Artificial Intelligence*. This framework recommends that providers and manufacturers of synthetic nucleic acids screen their sequences and customers before fulfilling orders to prevent potential misuse.

The form will collect basic organizational information and an attestation of compliance from providers and manufacturers of synthetic nucleic acids and benchtop nucleic acid synthesis equipment. This includes organization name, location, website, and type of organization. The form also includes primary and secondary contact information such as name, location, phone number and email address to ensure there is a point of contact with the company in case of questions regarding compliance and record keeping. This data is needed to ensure the self-attestation form can be filed and logged correctly, and to ensure the government can reach out to the correct contact if clarification if necessary.

This data collection is developed by NSC and OSTP and is submitted by CDC on their behalf.

A2. Purpose and Use of the Information Collection

The attestation form provides a streamlined process for compliance with the Framework for Providers and Manufacturers. Information collected may be used to document and ensure compliance with the Framework. Federal agencies that conduct or fund life sciences research may collect this form or treat it as a valid attestation of compliance with terms and conditions as required by the *Executive Order on the Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence.*

A3. Use of Improved Information Technology and Burden Reduction

The template will be available for all Providers and Manufacturers. Utilization of the template will help provide a standardized way for providers to attest compliance with the Framework.

Every effort has been made to limit the burden on individual respondents who use this form. The form will be posted online or shared electronically with customers and federal funding agencies upon request. Respondents may choose whether to post the form publicly or share it upon request, reducing burden by enabling respondents to use the form however they so choose.

The annualized burden hours for collectively completing work plan template, cooperative agreement work plan template, and the evaluation work plan template are estimated at twenty hours total as detailed below.

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 (in hours)**
Providers and manufacturers of synthetic nucleic acids and bench top nucleic acid synthesis equipment	Annual Provider and Manufacturer Self-Attestation Statement	60	1	20 minutes	20 hours

A4. Efforts to Identify Duplication and Use of Similar Information

This self-attestation form was developed as part of an interagency collaboration effort that was coordinated by the White House Office of Science and Technology Policy. The interagency discussions confirmed the government has no duplicative template, form, or data request for the providers and manufacturers in question. There is a university-based list of gene synthesis suppliers (https://app.smartsheet.com/b/publish?EQBCT=fb553d5809c3446bafe038f3f601b543) but this is not for official use.

A5. Impact on Small Businesses or Other Small Entities

This template is a voluntary form that business may choose to use but are not obligated to use to attest compliance with the Framework. The proposed form will therefore have no additional impact on small businesses or small entities beyond the requirements established in the Framework, and will simplify the processes required by the Framework.

A6. Consequences of Collecting the Information Less Frequently

Updating the form will be an annual requirement. Lowering the update frequency would increase the likelihood that the forms come out of date.

A7. Special Circumstances Relating to the Guidelines of 5 CRF 1320.5

This request fully complies with the regulation 5 CFR 1320.5.

A8. Comments in Response to the FRN and Efforts to Consult Outside the Agency

Part A: PUBLIC NOTICE
A 60-day Federal Register Notice was published in the Federal Register (CDC Docket No. CDC-2024-0056) on 25 July 2024. (**Attachment 2**).

To date the CDC has not received any public comments and the comment period will close on 24 September 2024. (**Attachment 2a**).

Part B: CONSULTATION

This template was developed and reviewed by the interagency working group on nucleic acid synthesis screening, coordinated by EOP (NSC and OSTP) and ASPR.

A9. Explanation of Any Payment or Gift to Respondents

No payment or gift to respondents will be offered.

A10. Protection of the Privacy and Confidentiality of Information Provided by Respondent

[The Privacy Act does not apply to this information collection. Activities do not involve the collection of sensitive or individually identifiable information (IIF). Although the contact information is obtained for each funded recipient (i.e. contractor), the contact person provides information about the organization, not personal information. Departments and agencies will determine whether and how to collect this form pursuant to relevant statute and their own authorities.]

A11. Institutional Review Board (IRB) and Justification for Sensitive Questions

This information collection is not Research involving Human Subjects. The form included in this package is not meant to be used in research activities. The federal government does not plan to conduct research using these forms. Instead, the purpose of the form is to help providers of synthetic nucleic acids and manufacturers of nucleic synthesis equipment make an attestation that they adhere to the Framework for Nucleic Acid Synthesis Screening. Therefore, the protocols associated with the forms included in this package are not subject to IRB review. The form does not include any sensitive questions.

A12. Estimates of Annualized Burden Hours and Costs

The attestation form is are the only data collection form for this project that is required for all awardees to complete.

Table A12A: Estimated Annualized Burden (Hours)

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
Providers and manufacturers of synthetic nucleic acids and bench top nucleic acid synthesis equipment	Annual Provider and Manufacturer Self-Attestation Statement	60	1	20 minutes	20 hours
	Total				**20**

The total annualized cost burden requested from respondents is $976.20, as summarized below in Table A12B. Estimates of the annualized cost burden to respondents for the collection of information are based on the Department of Labor Bureau of Labor Statistics “May 2022 National Occupational Employment and Wage Estimates, United States” (see https://www.bls.gov/oes/current/oes_nat.htm#19-0000). The occupation title and hourly wage of employees who will complete the information collection varies by awardee type, including academic centers, jurisdictions, and private consulting firms. For the purpose of this cost burden analysis, a proxy occupation was used to represent the average employee involved in the information collection. The mean hourly wage for Life Scientists, All Other is $48.81.

Table A12B Hourly Wage Estimates for Life Scientists, All Other

Occupation Code	Occupation Title	Mean Hourly Wage
19-1099	Life Scientists, All Other	$48.81

A13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

There will be no direct costs to the respondents other than their time to fill out the form. Capital and start-up costs will not be required for this information collection.

A14. Annualized Cost to the Federal Government

The annualized cost to the federal government of reviewing the self-attestations each year is estimated at $4,881.

Number of providers and manufacturers with forms	Time to review forms	Number of agencies	Cost per hour	Total Cost
60	10 minutes	10	$48.81	$4,881

A15. Explanation for Program Changes or Adjustments

This is a new information collection.

A16. Plans for Tabulation and Publication and Project Time Schedule

OSTP will release the form once it is cleared for public use. The Federal Government may utilize the form to monitor compliance with the Framework.

A17. Reason(s) Display of OMB Expiration Date is Inappropriate

The display of the OMB expiration date is appropriate.

A18. Exceptions to Certification for Paperwork Reduction Act Submission

There are no exceptions to the certification.

List of Attachments

Attachment 1 – OSTP Framework for Nucleic Acid Synthesis Screening

Attachment 2 – Federal Register Notice