

Supporting Statement A for

NIH COVID-Vaccination Attestation Intake Form (ORS)

OMB# 0925-XXXX Expiration date: XX/XXXX

August 25, 2021

Check off which applies:

- New
- Revision
- Reinstatement with Change
- Reinstatement without Change
- Extension
- ✓ Emergency
- Existing w/o OMB approval

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Attachments

1. NIHCOVID-19 Vaccine Attestation instrument
2. PIA - NIDDK On-Site Web and Apps
3. PiaFrm_Privacy Module NSAT Annual Review

A. Justification

The NIH now has a mandatory vaccination requirement that affects several thousand staff. We have been providing contractors, tenants, fellows and other staff access to testing and vaccines during this pandemic. The information to be collected is needed to ensure we have the vaccination details for our staff (i.e. those providing essential services to the NIH via use agreements, visiting scientists, fellows and contractors, food service providers and our three separate childcare providers) to properly offer booster shots, and to match original shot provided (if required). This information is also critical so we can plan which vaccines we need to have on hand for booster administration to staff. We are not yet sure if the vaccines will be interchangeable. Knowing the manufacturer will allow us to plan and administer in a proactive way, ensuring compliance with EUA and medical requirements. All this information will flow into our electronic health information system and become part of their OMS record, similar to the influenza program we also administer. The dates included in this form will allow us to ensure equitable scheduling in order with the timeframe in which the original vaccination was administered. The information on the boosters is that they will be due 8 months after initial dose series completion. Without this information we cannot schedule in an equitable manner for those vaccinated within the community, even if they are subject to the mandatory requirements and work on site daily. We are including a check box for medical or religious declination and an uploaded signature page, consistent with the mandatory policy mirroring the one we currently have in place for influenza.

A.1 Circumstances Making the Collection of Information Necessary

The U.S. Office of Personnel Management (OPM) approved the U.S. Department of Health and Human Services' (HHS) request for a variation to a strict application of 5 CFR 339.205 under 5 CFR.1 to promote the efficiency of the Government. Under this variation, HHS may use the authority under 5 CFR 339.205 to mandate COVID-19 vaccinations authorized under Emergency Use Authorizations (EUA) for its patient-facing health care personnel, including its health care applicants and employees, who work in Indian Health Service (IHS) medical facilities, National Institutes of Health (NIH) clinical research facilities, or other HHS facilities that provide direct patient care or clinical research. In addition, the Safer Federal Workforce Task Force created by President Biden's Executive Order 13991 has instructed Federal Agencies to inquire about the COVID-19 vaccination status of federal employees and on-site contractors. The NIH now has a COVID-19 vaccination requirement for those with patient contact, or probable patient contact, and all persons working in Building 10 on the Bethesda campus. The proposed information collection will be used to ensure compliance with the above mentioned requirements, mandatory vaccine policies, to generate the list of persons required to be tested on a routine basis, and will provide important information regarding safety frameworks, guidance, and procedures. We will be submitting a regular submission to allow data collection for three years anticipating continued need for this information.

The purpose of the information collection is to promote the safety of the Federal workplace consistent with the below-referenced authorities, the COVID-19 Workplace Safety: Agency Model Safety Principles established by the Safer Federal Workforce Task Force, and guidance from the Centers for Disease Control and Prevention (CDC) and the Occupational Safety and Health Administration (OSHA).

Authority: Pursuant to 5 C.F.R. § 339.205, OPM authorizes agencies to establish immunization programs for employees who are exposed to significant health or safety risks by nature of their work. For contractors, trainees, and volunteers, HHS has adequate authority to impose these vaccination requirements. NIH policy "Mandatory COVID-19 Immunization for NIH Staff who have Patient Contact." The legal authority to operate and maintain a Privacy Act System of Records is 42 U.S.C. 241 and 5 U.S.C. 7902.

A.2 Purpose and Use of the Information Collection

The NIH is collecting COVID-19 vaccination attestations from all personnel to comply with the Safer Federal Workforce Task Force. Additionally, COVID-19 vaccination is mandated NIH-wide for patient facing staff and those that may come in to contact with patients, as well as anyone working in Building 10 on the NIH campus. Responses to the NIH COVID-19 Vaccination Attestation intake form will be submitted electronically through the REDCap System (Research Electronic Data Capture). The Personally Identifiable Information (PII) about the individual will be stored in the OMS Electronic Health Record (EHR). This survey will be used for existing staff, as well as newly onboarded staff in the coming months. This information will be maintained for the duration of employment plus 30 years to comply with the Occupational Safety and Health Administration requirements for medical records.

NIH recognizes that this emergency submission only authorizes data to be collected for six months following the approval date and will conform with this regulation.

In order to continue to respond to this national public health emergency through the routine collection of data, we will begin the process of developing and submitting a separate full clearance package for the OMB's consideration following the completion of this six-month emergency clearance.

A.3 Use of Information Technology and Burden Reduction

Responses to the OMS-COVID-19 Vaccination Status Attestation intake form are submitted electronically through the REDCap System (Research Electronic Data Capture). REDCap is a secure web application for building and managing research databases and online surveys. Using the online REDCap system reduces the time and burden for respondents in comparison to using a paper-based collection. NIH Privacy Impact Assessment (PIA) BTRIS: REDCap P-8609195-310411

The Personally Identifiable Information (PII) about the individual will be stored in the Office of Medical Service (OMS) Electronic Health Record (EHR). The OMS EHR is a government application. The OMS EHR application is hosted on internal servers operated by the Office of Research Services (ORS), Office of Innovation and Information Technology (OIIT) and by the National Institutes of Health Clinical Center's (NIH/CC) Department of Clinical Research Informatics (DCRI). NIH PIA OD ORS PI Dashboard/HealthRx Nexus P-5860043-506903.

A.4 Efforts to Identify Duplication and Use of Similar Information

The NIH is using previously captured voluntary attestations to populate the records for this new requirement. Former respondents will only be requested to verify the information previously submitted using a unique link emailed to them. We have taken the common OMB form, and adapted it to an electronic database to decrease the administrative burden, and to streamline reporting into our case management system, for compliance and because we needed to add several fields to comply with our mandatory vaccine program. The use of this data collection tool will streamline our ability to offer booster shots, and will be a more automated process rather than email or paper based information. Not all OPDIVs have this mandatory program, and our needs are unique compared to others in the federal government.

A.5 Impact on Small Businesses or Other Small Entities

All data collection efforts will be conducted with individuals; thus this will not impact small businesses.

A.6 Consequences of Collecting the Information Less Frequently

If this information collection is not conducted, or conducted less frequently, the result may be a spread of the COVID-19 virus, serious illness and fatalities in the patient, health care worker, and employee population working in Building 10. In addition, the NIH will not be in compliance with 5 CFR 339.205 mandating COVID-19 vaccinations, authorized under Emergency Use Authorizations (EUA), for its patient-facing health care personnel, including its health care applicants and employees.

A.7 Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

In response to the national public health emergency, the NIH as a federal health and research entity, must comply with 5 CFR 339.205 to mandate COVID-19 vaccinations authorized under Emergency Use Authorizations (EUA) for its patient-facing health care personnel, including its health care applicants and employees. In response we are requesting emergency clearance for this data collection. Thus, this collection will not go through a 60-day public comment period and will only undergo a 30-day public comment period after clearance has been granted. The team is also submitting an information collection request for full review to continue collecting data after the six-month Emergency Clearance approval period.

Emergency Clearance for the NIH COVID-19 Vaccination Attestation Intake Form will allow the NIH to measure and monitor all persons requiring COVID-19 vaccination due to their patient contact, or probable patient contact in Building 10 on the Bethesda campus. The proposed information collection will be used to ensure compliance with these requirements, generate the list of persons required to be tested on a routine basis, and will provide important information regarding safety frameworks, guidance, and procedures. This information collection and clearance will comply with the guidelines as laid out in 5 CFTR 1320.5.

A.8.1 Comments in Response to the Federal Register Notice

This is an emergency request; an emergency FRN was published on Monday, August 30, 2021, (Vol. 86, pg. 48432) and allowed 10 days for public comment. No public comments were received.

A.8.2 Efforts to Consult Outside Agency

The NIH COVID-19 Attestation Intake Form is based on the template provided by the Safer Federal Workforce Task Force.

A.9 Explanation of Any Payment of Gift to Respondents

None

A.10 Assurance of Confidentiality Provided to Respondents

The Personally Identifiable Information (PII) collected in this form will be stored in the individual's OMS Electronic Health Record (EHR). The OMS EHR, a government application, is hosted on internal servers

operated by the Office of Research Services (ORS), Office of Innovation and Information Technology (OIIT) and by the National Institutes of Health Clinical Center's (NIH/CC) Department of Clinical Research Informatics (DCRI). Both the REDCap and the EHR systems, where information is taken in and stored, undergo annual privacy impact assessments to ensure all privacy controls are up to date. The SORN for this system is [09-25-0166 Radiation and Occupational Safety and Health Management Information Systems, HHS/NIH/ORS.](#)

Authority: Pursuant to 5 C.F.R. § 339.205, OPM authorizes agencies to establish immunization programs for employees who are exposed to significant health or safety risks by nature of their work. For contractors, trainees, and volunteers, HHS has adequate authority to impose these vaccination requirements. NIH policy "Mandatory COVID-19 Immunization for NIH Staff who have Patient Contact." The legal authority to operate and maintain this Privacy Act System of Records is 42 U.S.C. 241 and 5 U.S.C. 7902.

A.11 Justification for Sensitive Questions

The questions asked in this form, specific to the manufacturer and dates of vaccination against COVID-19 disease may be sensitive but are important for multiple reasons. The first is that as part of our mandatory vaccine program, modeled after our mandatory influenza program, requires the dates and manufacturer of the vaccine received to ensure it complies with the requirements in that program. Additionally, this data will allow us to equitably invite persons for booster shots, if needed, or available. As the pandemic shifts, if booster shots are required to maintain full vaccination compliance, we need to know when they were vaccinated initially to ensure compliance with the timeliness of the booster administration. All data will be stored in our OMS electronic health record system. The data collection use and storage will be communicated in the landing page of this form, as well in the privacy act notice that must be acknowledged prior to use of the form. Additionally, NIH wide communications will be sent to all staff to explain the intent of this form and the maintenance of this data.

A.12.1 Estimates of Hour Burden Including Annualized Hourly Costs

Table 12-1
Estimated Annualized Burden Table

Type of Collection	No. of Respondents	No. Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
NIH COVID-19 Vaccine Attestation intake form	31,000	1	5/60	2,583
Total		31,000	2,583

A.12-2 ANNUAL COST TO RESPONDENT

Provide estimates of annualized cost to respondents for the hour burdens for collections of information, identifying and using appropriate wage rate categories. The cost of contracting out or paying outside parties for information collection activities should not be included here.

Table 12-2 Annualized Cost to Respondents

Type of Respondents	Total Annual Burden Hours	Hourly Respondent Wage Rate*	Respondent Cost
Individual (tenants, fellows, Contractor)	2,583	38.15	98, 541
TOTAL	2,583		\$98,541

*Bureau of Labor Statistics: The hourly rate for Life, Physical and Social Sciences occupations was obtained from the https://www.bls.gov/oes/2020/may/oes_nat.htm#19-0000 and was used for this calculation.

A.13 Estimate of Other Total Annual Cost Burden to Respondents or Record Keepers

Not applicable

A.14 Annualized Cost to the Federal Government

Cost Descriptions	Grade/Step	Salary*	% of Effort	Fringe (if applicable)	Total Cost to Gov't
Federal Oversight					
RedCap Lead	GS-13/6	\$ 120, 972	10		\$12,097
Data Lead	GS-13/6,	\$ 120,972	10		\$12,097
Privacy Lead	T-42	\$ 178,500	5		\$8,925
Privacy Lead 2	GS-14/6	\$ 140,950	5		\$7,048
Contractor Cost					
Nurse document review		\$ 151,840	12.5		\$18,980
Nurse document review		\$ 151,840	12.5		\$18,980
Nurse document review		\$ 151,840	12.5		\$18,980
Nurse document review		\$ 151,840	12.5		\$18,980
Travel					
Other Cost					

Total					\$122,137
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*the Salary in table above is cited from <https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/21Tables/html/DCB.aspx>

A.15 Explanation for Program Changes or Adjustments

This is a new information collection request

A.16 Plans for Tabulation and Publication and Project Time Schedule

A.16 - 1 Project Time Schedule	
Activity	Time Schedule
Surveys sent to Respondents	1 week - 6 months after OMB approval
Analyze Responses	1 week - 6 months after OMB approval
Preparation of compliance reports	1 month-6 months after OMB approval

A.17 Reason(s) Display of OMB Expiration Date is Inappropriate

The OMB control number will be displayed (expiration date).

A.18 Exceptions to Certification for Paperwork Reduction Act Submissions

None