

Supporting Statement A for
NIH COVID-19 Vaccination Status Form (ORS)

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ATTACHMENTS

1. NIHCOVID-19 Vaccination Status instrument
2. PIA - NIDDK On-Site Web and Apps
3. PIA Form, Privacy Module NSAT Annual Review
4. Screening Questionnaire
5. Building Access Form

A. ABSTRACT

Executive Order 14043 *Requiring Coronavirus Disease 2019 Vaccination for Federal Employees* requires that each agency implement a program to require COVID-19 vaccination for all Federal employees. Executive Order 14042 *Ensuring Adequate COVID Safety Protocols for Federal Contractors* requires that parties that contract with the Federal Government comply with guidance published by the Safer Federal Workforce Taskforce. Additionally, 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. Due to the uncertainties of the pandemic and the need maintain a safe work environment, we are requesting approval of a revision of this information collection for 3 years. The information to be collected is needed to ensure we have the vaccination details for our staff (e.g., 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 comply with Executive Order 14042, Executive Order 14043, and U.S. Department of Health and Human Services' (HHS) policy to mandate COVID-19 vaccinations for patient facing health care staff. This revision request includes two new forms as NIH is implementing a building entry protocol (Attachment 5) where all people, federal government employees, contractors, patients, and visitors, will walk up to a door and scan a QR code with their phone and answer screening questions (Attachment 4) about Covid exposure every day.

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, Executive Order 14043 instructed Federal Agencies to implement a program to require COVID-19 vaccination of all its Federal employees, with exceptions only required by law. Executive Order 14042 requires Federal Agencies to ensure that contracts and contract-like instruments include a clause to require the contractor to comply with all applicable guidance published by the Safer Federal Workforce Task Force created by President Biden's Executive Order 13991. 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 mandatory vaccine policies.

The purpose of the information collection will continue to ensure the safety of the Federal workplace consistent with Executive Order 14042 Ensuring Adequate COVID Safety Protocols for Federal Contractors, Executive Order 14043 Requiring Coronavirus Disease 2019 Vaccination for Federal Employees, 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: Executive Order 14042; Executive Order 14043; and 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 status from all personnel to comply with vaccination requirements in the authorities above, generate the list of persons required to be tested on a routine basis, and gather important information regarding safety frameworks, guidance, and procedures. 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 Status Form (Attachment 1) (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 Occupational Medical Service COVID Response Case Management System (OMS CMS). This form will be used for existing staff, as well as newly onboarded staff for the duration of the Executive Order. This information will be maintained for the duration of employment plus 30 years to comply with OSHA requirements for medical records.

Beginning soon, all non-patient NIH visitors will be required to attest to their vaccination status. This will be occurring at all NIH-owned facilities and certain leased facilities. All visitors who are not fully vaccinated must provide proof of a negative COVID-19 test result within the last 72 hours.

Contractors will be encouraged to upload proof of vaccination to OMS (<https://go.usa.gov/xtBUg>). Once OMB approval is granted, NIH will begin the process of deactivating PIV card physical access privileges for contractors who elect not to upload proof of vaccination. Those individuals will need to enter through an NIH visitor entrance where they will be required to verbally attest to their primary vaccination status. If a contractor reports they are unvaccinated or partially vaccinated or chooses not to report their vaccination status, they will be required to provide a physical or digital negative COVID-19 test result within the last 72 hours to gain access to the facility.

A.3 Use of Information Technology and Burden Reduction

Responses to the NIH-COVID-19 Vaccination Status Form are submitted electronically through the REDCap System (Research Electronic Data Capture) see attachment 2. 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 see attachment 3.

The Personally Identifiable Information (PII) about the individual will be stored in the OMS CMS. The OMS CMS is a government application hosted on internal servers operated by the Office of Research Services' (ORS) Office of Innovation and Information Technology (OIIT). NIH PIA OMS CMS: P-3416938-277234.

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

The NIH is using previously captured voluntarily submitted vaccination information to populate the records for this new requirement. Former respondents will only be requested to verify the information previously submitted, add the location of vaccination, lot number (if known) and upload proof of vaccination 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.

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 is not collected, or collected less frequently, it may result in workplace 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 Executive Order 14042, Executive Order 14043, and 5 CFR 339.205 which 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 addition, staff who do not comply may face disciplinary action.

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

No special circumstances. This information collection and clearance will comply with the guidelines as laid out in 5 CFR 1320.5.

A.8.1 Comments in Response to the Federal Register Notice

No comments were received.

A.8.2 Efforts to Consult Outside Agency

The NIH COVID-19 Vaccination Status 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 OMS CMS. The OMS CMS, a government application, is hosted on internal servers operated by the Office of Research Services' (ORS) Office of Innovation and Information Technology (OIIT). Both the REDCap and the OMS CMS systems, where information is taken in and stored, undergo annual privacy impact assessments to ensure all privacy controls are up to date. The system of record notices (SORN) referenced for these systems are [09-25-0166 Radiation and Occupational Safety and Health Management Information Systems, HHS/NIH/ORS; 09-40-0002, Public Health Service \(PHS\) Commissioned Corps General Personnel Records and OPM/GOVT-10, Employee Medical File System Records.](#)

Authority: Executive Order 14042; Executive Order 14043; and 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 and proof of vaccination 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 vaccination 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, based on requirements and availability and ensure that staff remain compliant with the requirement to be fully vaccinated. 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 CMS. 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

The average estimate for visitors, patients, construction workers and delivery people are 1,500 from September 2021 to December 2021 as measured by people screened at NIH Commercial Vehicle Inspection Facility. We anticipate these numbers to increase as return to the physical workplace will increase in the coming months as more persons including federal staff will return onsite.

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 Status Form	31,000	1	5/60	2,583
Screening Questionnaire	35,500	1	5/60	2,958
Building Access Form	35,500	1	5/60	2,958
Total		102,000	8,499

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 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	\$ 124,626	10		\$12,463
Data Lead	GS-13/6,	\$ 124,626	10		\$12,463
Privacy Lead	T-42	\$ 178,500	5		\$8,925
Privacy Lead 2	GS-14/6	\$ 147,272	5		\$7,364
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					\$117,135

*the Salary in table above is cited from <https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/22Tables/html/DCB.aspx>

A.15 Explanation for Program Changes or Adjustments

Adjustments have occurred since this submission was approved under an “emergency “procedures. The increase in burden of 5,916 hours is due to the addition of two new forms as NIH is implementing a building entry protocol where ALL people, feds, contractors, patients, and visitors, will walk up to a door and scan a QR code with their phone and answer screening questions about Covid exposure every day.

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