COVID-19 VACCINE SCREENING AND IMMUNIZATION DOCUMENTATION

OMB No. 0720-0068
OMB approval expires: July 31, 2021

PRIVACY ACT STATEMENT

AUTHORITY: DHA-IPM 20-004, "DoD Coronavirus Disease (COVID-19) Vaccination Program Implementation"; Public Law 104-191, 10 U.S.C., Chapter Ch. 55, Medical and Dental Care;

PURPOSE: To determine if the COVID-19 vaccine can be administered to the patient.

ROUTINE USES: Information in your records may be disclosed to other components within the MHS for the purpose of continuing medical care and determining military readiness. Additionally, this information may be shared with the Departments of Veterans Affairs and Health and Human Services and other local, state, and federal public health agencies for the purposes of satisfying public health and vaccination reporting requirements and responding to the COVID-19 pandemic.

Any protected health information (PHI), including mental health and substance abuse information, in your records may be used and disclosed generally as permitted by the HIPAA Privacy Rule (45 CFR Parts 160 and 164), as implemented within DoD by DoDM 6025.18. Permitted uses and disclosures of PHI include, but are not limited to, treatment, payment, and healthcare operations. A complete listing of the applicable routine uses may be found in the associated System of Records Notice (SORN).

APPLICABLE SORN: EDHA 07, Military Health Information System (June 15, 2020, 85 FR 36190) https://dpcld.defense.gov/Portals/49/Documents/Privacy/SORNs/DHA/EDHA-07.pdf

DISCLOSURE: Voluntary. If you choose not to provide your information, no penalty may be imposed, but there may be a delay in the appropriate medical entry in your electronic health record.

1. NAME *(Last, First, Middle Initial)*	2. DoD ID or Unique Identifier	3. DATE OF BIRTH *(YYYYMMDD)*	4. AGE

5. CATEGORY: ☐ Service Member ☐ Beneficiary ☐ Civilian Contractor ☐ Civilian Employee ☐ Other

PART I – COMPLETED BY PATIENT	**YES**	**NO**
(1) Would you like to speak with a healthcare team member about the COVID-19 vaccine before deciding whether or not to receive the vaccine?	☐	☐
(2) After reviewing the offered education material, would you like to receive the COVID-19 vaccine today? *(if you are declining the vaccine you may skip questions 3-12 and sign block 6)*	☐	☐
(3) Do you have a medical condition that places you at high risk for a serious COVID-19 disease outcome as defined by the CDC?	☐	☐
(4) Are you currently sick, feel ill, or have a fever over 100°F?	☐	☐
(5) Have you received a COVID-19 vaccine before? If so, which one _____ Date _____	☐	☐
(6) Have you had an adverse or allergic reaction to a prior COVID vaccine, anaphylaxis due to any cause, or allergic reaction to any other vaccine or injectable therapy?	☐	☐
(7) Do you have hemophilia or other bleeding disorder or take a blood thinner?	☐	☐
(8) Are you, or might you be, pregnant or are you nursing (breastfeeding)?	☐	☐
(9) Do you have an immunocompromising condition (HIV/AIDS, cancer, leukemia, etc.) or take an immunocompromising medicine or treatment (steroids, chemotherapy, radiation therapy, etc.)?	☐	☐
(10) Will you be TDY/TAD/PCS OCONUS for > 30 days within the next 30 days?	☐	☐
(11) Have you received any vaccine in the past 14 days or plan to receive any vaccine in the next 14 days?	☐	☐
(12) Have you received a monoclonal antibody preparation (Regeneron™) or Convalescent Plasma within the past 90 days?	☐	☐

6. ACKNOWLEDGMENT

I have read or had explained to me the information in the Coronavirus Vaccine Emergency Use Authorization (EUA) Fact Sheet.
I have also had a chance to ask questions, and they were answered to my satisfaction.

a. PATIENT / GUARDIAN SIGNATURE: _____ b. DATE: _____

PART II – COMPLETED BY SCREENER

7. ASSESSMENT
- ☐ Give COVID-19 vaccine - **dose #1** today.
- ☐ Give COVID-19 vaccine - **dose #2** today.
- ☐ Do not give COVID-19 vaccine today.
- ☐ Refer to experienced provider for further evaluation

8. Vaccine Information Material provided *(check box)*
- ☐ EUA Vaccine Fact Sheet for Vaccine Recipients

9. SCREENER INFORMATION

a. NAME b. DATE *(YYYYMMDD)*

PART III – COMPLETED BY VACCINATOR

10. VACCINE ADMINISTERED
- ☐ Pfizer COVID-19 vaccine (≥ 16 yrs of age) 0.3mL IM
- ☐ Moderna COVID-19 vaccine (≥ 18 yrs of age) 0.5mL IM

11. LOT #: _____

12. EXPIRATION DATE: *(YYYYMMDD)*

13. DOSE: ☐ 0.3 mL IM ☐ 0.5 mL IM

14. SITE: ☐ Left Deltoid ☐ Right Deltoid

15. COMMENTS:

16. VACCINATOR INFORMATION a. NAME: b. DATE: *(YYYYMMDD)*

17. ASIMS / MEDPROS / MRRS / AHLTA / MHS GENESIS Entry a. NAME: b. DATE: *(YYYYMMDD)*

Information for Healthcare Professionals about Screening Questions

(1) Would you like to speak with a healthcare team member about the COVID-19 vaccine?

COVID-19 vaccination is voluntary. These are new vaccines for which there are, understandably, many questions. The potential vaccinee should be afforded ample opportunity to read the FDA-provided EUA Vaccine Fact Sheet and to ask questions prior to vaccination. The staff will not hesitate to refer an individual to an experienced healthcare provider to address questions or concerns regarding the vaccine.

(2) After reviewing the offered education material, would you like to receive the COVID-19 vaccine today?

An individual, after having reviewed the EUA Vaccine Fact Sheet and having had all questions addressed, may decline receipt of a COVID-19 vaccine without any impact upon their future healthcare within the Military Health System or their military career. For declining Service personnel, their declination will be entered into their electronic health record and/or Services' Immunization Tracking System using the exemption code MD (medical, declined).

(3) Do you have a medical condition that places you at high risk for a serious COVID-19 disease outcome as defined by the CDC?

If an individual does not have a health condition listed by the CDC that places them at high risk for a serious COVID-19 disease outcome, they remain prioritized for COVID-19 immunization within their job/position or other health category.

(4) Are you currently sick, feel ill, or have a fever over 100°F?

People with moderate or severe illness should not be vaccinated until their symptoms improve. Mild illnesses, even with fevers or requiring antibiotics, should not preclude receipt of COVID-19 vaccine. There is no evidence that acute illness reduces vaccine efficacy or increased vaccine adverse events.

(5) Have you received a COVID-19 vaccine before? If so, which one_____? Date_____?

The CDC recommends that different brands of COVID-19 vaccine not be mixed. Therefore, every effort should be made to ensure that when a vaccinee receives the first shot of one brand of vaccine that he/she be able to receive the same brand about 21-28 days later. If an individual is a participant in a COVID-19 Vaccine Trial, they should indicate 'yes' to this question and for "which vaccine" state "UNKNOWN". Direct such trial participants to contact their Study's Director to learn whether they received the active vaccine or an inactive placebo and to receive further counseling and guidance from the Study Director before receiving an authorized COVID-19 vaccine. If a study participant chooses to receive the authorized vaccine, it is recommended these two different COVID-19 vaccines be separated by a minimum of four weeks.

(6) Have you had an adverse or allergic reaction to a prior COVID vaccine, anaphylaxis due to any cause, or allergic reaction to any other vaccine or injectable therapy?

Patients reporting a serious reaction to a previous dose of COVID-19 vaccine, any vaccine, or injectable therapy (intramuscular, intravenous, or subcutaneous), should be asked to describe their symptoms. There is a remote chance that a COVID-19 vaccine could cause a severe allergic reaction. (1) Persons who have had a severe allergic reaction to the first dose of a COVID-19 vaccine should not receive further doses. (2) An allergic reaction to any other vaccine or injectable therapy (such as chemotherapeutic agents) is a precaution to COVID-19 vaccination. Such individuals should be counseled that the risk of COVID-19 vaccine in such a setting is unknown and they should seek the advice of a, or their, medical specialist. If these individuals or for those with a history of anaphylaxis for any other cause elect to be vaccinated, , they should be observed for 30 minutes afterward. (3) A history of a significant, non-anaphylactic, reaction to a non-injectable medicine, food, latex, or pollen allergy does not preclude receipt of a COVID-19 vaccine. Non-allergic, flu-like symptoms (malaise, myalgia, other systemic symptoms), and vaccination site reactions have been reported with COVID-19 vaccines. These mild-to-moderate reactions are not a reason to withhold future vaccination. However, moderate-to-severe non-allergic reactions should be evaluated by an experienced provider prior to vaccination.

(7) Do you have hemophilia or other bleeding disorder or take a blood thinner?

People with bleeding disorders or treated with blood thinners should be counseled that they may have an increased risk of developing a hematoma following any intramuscular injection. If feasible, intramuscular vaccination may be delayed until shortly after anti-hemophilia therapy or alternation in their blood thinner regimen. Alternatively, a fine needle (≤ 23 gauge) can be used for vaccination and firm pressure applied to the site (without rubbing) for at least 2 minutes.

(8) Are you, or might you be, pregnant or are you nursing (breastfeeding)?

If a woman is part of a group (e.g., healthcare personnel) who is recommended to receive a COVID-19 vaccine and is pregnant, she may choose to be vaccinated. However, pregnant or nursing women should be counseled that the new COVID-19 vaccines have not yet been tested for safety or efficacy during pregnancy or nursing (breastfeeding).

(a) Pregnancy. Safety and Efficacy of COVID-19 vaccines in pregnant women is as of yet unknown. Animal developmental and reproductive toxicity studies are ongoing. In general, there is no evidence that inactivated vaccines pose a risk to a fetus or pregnant woman. Currently, COVID-19 vaccines approved for use by the FDA are considered inactivated vaccines. Nonetheless, a cautious approach is warranted with COVID-19 vaccines in pregnancy. An individualized risk/benefit analysis should take into account the pregnant woman's risk of exposure to COVID-19, the risks of COVID-19 to her and potential risks to the fetus, and the unknown risks associated with the vaccine. Routine testing for pregnancy prior to receipt of a COVID-19 vaccine is not recommended. A vaccinated pregnant woman should be encouraged to speak with her OB Provider about enrolling in a COVID-19 Pregnancy Registry.

(b) Breastfeeding. No vaccines are considered a risk to a woman or her breastfeeding child, with the special exceptions of smallpox and yellow fever vaccines. However, because COVID-19 vaccines are new, patients should be counseled that these vaccines have not been tested in breastfeeding women. Counseling may include noting that CDC/ACIP does not require breastfeeding-specific data to consider other vaccines safe in breastfeeding. In general, the benefits of vaccinating nursing women usually outweigh potential risks when the likelihood of disease exposure is high and when infection would pose a risk to the mother.

(9) Do you have an immunocompromising condition (HIV/AIDS, cancer, leukemia, etc.) or take an immunocompromising medicine or treatment (steroids, chemotherapy, radiation therapy, etc.)?

Immunocompromised individuals should be counseled that neither the safety nor efficacy of the COVID-19 vaccines have been studied in individuals with weakened immune systems resulting from congenital defect, disease, medications, or treatments. Non-live COVID-19 vaccines (those currently approved or under study in the US) may be administered to immunocompromised patients, although the protective benefit may be suboptimal. Vaccinated immunocompromised individuals need to continue to follow all current guidance to protect themselves against COVID-19.

(10) Will you be TDY/TAD/PCS OCONUS for > 30 days within the next 30 days?

The CDC recommends that different brands of COVID-19 vaccine not be mixed. Therefore, every effort should be made to ensure that when a vaccinee receives the first shot of one brand of vaccine that he/she be able to receive the same brand about 21-28 days later. Extended OCONUS travel within 30 days of the first vaccination generally precludes this. Therefore, if such travel is planned, if the screener cannot ensure the 2nd dose with same brand can be administered at new location, initiation of vaccination should be deferred to the new location.

(11) Have you received any vaccine in the past 14 days or plan to receive any vaccine in the next 14 days?

Currently there is no data on safety or efficacy of a COVID-19 vaccine administered with other vaccines, however, the ACIP recommends that COVID-19 vaccines be administered alone with a minimum interval of 14 days before or after administration with any other vaccines. Vaccines required for post-exposure prophylaxis (e.g., rabies vaccine) may be administered within the 14-day period. Additionally, providers and patients can consider other vaccines, including the influenza vaccine, within the 14-day window on a case-by-case basis with shared clinical decision-making for Force Health Protection and other important co-administration vaccination needs.

(12) Have you received a monoclonal antibody preparation (Regeneron™) or Convalescent Plasma within the past 90 days?

Currently there is no data on safety or efficacy of COVID-19 vaccination in persons who received monoclonal antibodies or convalescent plasma as part of COVID-19 treatment, however the ACIP recommends that COVID-19 vaccination be deferred for 90 days after receipt to avoid a possible impact on COVID-19 vaccination by prior antibody treatment. However, providers and patients can consider COVID-19 vaccination in such treated individuals within this 90-day window on a case-by-case basis with shared clinical decision-making for Force Health Protection and other important vaccination needs.

The Defense Health Agency-Immunization Healthcare Division (DHA-IHD) is available to assist patients and healthcare providers with treatment of health problems before and after vaccinations, and with medical exemptions.
Please contact the DHA-Immunization Healthcare Division 24/7 Support Center at 877-438-8222, DSN 761-4245.

AGENCY DISCLOSURE NOTICE

The public reporting burden for this collection of information is estimated to average 10 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden, to the Department of Defense, Washington Headquarters Services, at whs.mc-alex.esd.mbx.dd-dod-informationcollections@mail.mil. Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number.