September 24, 2020

Veterans Health Administration (VHA) Office of Research and Development (ORD) Guidance on VA Employee Participation in VA-Conducted COVID-19 Research Studies

Scope: The scope of this guidance relates to the participation of VA employees in VA conducted COVID-19 research studies. This guidance is intended for VA leadership whose employees are recruited for these research studies and for the research study teams to assist them in answering questions of potential employee research participants.

Background: In response to requests from VA employees, on September 4, 2020, and in consultation with VHA Labor and Management Relations and Office of General Counsel, Dr. Richard Stone, the VHA Executive in Charge, conveyed information to VHA Network Directors about enrollment opportunities of COVID-19 research studies to Veteran and non-Veteran VA employees. This same information was shared with Union leadership on September 8, 2020. The message encouraged VHA research teams and facilities to allow all VA employees, including those who are not Veterans, the opportunity to volunteer for VA-conducted COVID-19 research to overcome the pandemic, such as clinical trials testing vaccine candidates. Local research teams, with the concurrence of facility leadership, make the decision of whether to open non-Veterans based on the clinical trials team's capacity.

Inclusion of Non-Veteran Employees: In accordance with 38 CFR 17.45, 17.92 and VHA Directive 1200.01 paragraph 13, a Research and Development Committee (R&DC) has the authority to approve the inclusion of non-Veterans in VA research studies subject to the requirements of the policy. The policy further states that non -Veterans may not enter into VA studies because a non-Veteran population is easily accessible to the investigator. For COVID-19 research studies, and the preventative vaccine trials in particular, the VA employees are not being included as a result of ease of access. Instead for VHA healthcare employees, their involvement would help ensure the successful testing of the vaccine against potential exposure. Many of the Veteran beneficiaries of VHA are not particularly desirable for these vaccine studies as they have proven effective in socially distancing and making use of telehealth capabilities.

Other Subject Payments and Compensation/Benefits: Not every study offers payments to subjects for their time and participation in a study or compensation for restitution or financial reparation in the event a research-injury occurs. The informed consent document approved by the Institutional Review Board (IRB) will contain study specific subject payment and compensation information. Each of the COVID-19 countermeasure studies is subject to the Public Readiness and Emergency Preparedness Act (PREP Act). On August 17, 2020, ORD issued guidance, "Implementation of the Public Readiness and Emergency Preparedness Act (PREP Act) for COVID-19 Research Activities", regarding the PREP Act's implementation for VA studies. The guidance can be found at this link : PREP Act. The PREP Act protects covered persons from legal actions by study subjects. All researchers conducting a COVID-19 study are highly encouraged to review this guidance and understand the parameters of the PREP Act exclusions. The Department of Health and Human Services (DHHS) Health Resources & Services Administration has established the Countermeasures Injury Compensation Program (CICP). An injured or harmed study subject may apply for benefits through this program. See CICP.

Notice to Unions: A notice was released to the leadership of VA Unions on September 8, 2020. Union leadership who have requested briefings have either had a briefing or a briefing is scheduled.

Unique Research Study Conditions: Each research study has unique procedures, potential risks and benefits, and VA employees are encouraged to fully review and have all their questions answered prior to volunteering for and enrolling in a study. Research study teams are to provide all available information to and answer all study related questions for prospective study participants. **Study participants may leave any study at any time without penalty to their VHA care, VA benefits, or status of employment.**

Research Related Injury/Cost of Treatment of Subject Injury: VHA Medical Center Directors have a responsibility to care for or arrange care for any VA subject injured by participation in a VA conducted, VA R&DC approved research study. This is irrespective of Veteran status and is addressed in 38 CFR 17.85 and VHA Directive 1200.05: Requirements for the Protection of Human Subjects in Research, Paragraph 24. For many of VA's COVID-related research studies, the cost of treating subject injury is the responsibility of the study Sponsor through the contractual terms of the Cooperative Research and Development Agreement (CRADA) or other similar legal agreement. When the cost of treating subject injury is the responsibility of a study Sponsor, the Medical Center first covers the cost and then is reimbursed for these costs subject to the legal agreement.

When the cost of treatment of subject injury has <u>not</u> been assigned through an agreement to a study Sponsor, Medical Center Directors should be cognizant of including non-Veterans when the study involves the use of a therapy such as a vaccine, drug or device and the study risk is determined by the IRB to be more than minimal risk. Studies where cost of treating subject injury has not been assigned to a study Sponsor and reimbursement is not sought, the Medical Center bears the burden for costs associated with the research related injury. ORD is responsible to cover these costs for studies funded by ORD in which ORD provided approval of the inclusion of non-Veterans. Medical Center leadership should review each study to understand the implications of cost of treating subject injury to the medical center regardless of whether the study involves Veterans or non-Veterans.

Guidance

1. **Are all VA employees eligible to participate in all VA conducted COVID-19 studies?**

   All employees are eligible subject to the following exceptions:

   a. The employee does not meet the study specific, IRB-approved criteria.
   b. Possible challenges regarding off duty recruitment and enrollment.

2. **Can an employee participate during his/her duty day?**

   No. If an employee is interested in participating, he/she may contact the study team and learn whether the study is accepting employee recruitment before and after duty hours and on breaks. An employee may also participate while on approved leave. No change in the conditions of employment may be made for participation in the study.

3. **Can VA Medical Center leadership or supervisors encourage their employees to participate in VA research studies?**

   No. To avoid the appearance of undue influence over any employee, Medical Center leadership and supervisors will not encourage employees to participate in any research study. Supervisors are not to track or inquire about the enrollment of employees in any research study**. Conditions of employment will not be changed for any employee who volunteers or does not volunteer for a COVID-19 study based on such a decision.** No VA employees can take time away from their duty day to engage in study activities. Employees are welcome to take annual leave to participate in study activities that would otherwise interfere with the performance of duty.

4. **Can VA Medical Center leadership and supervisors volunteer to participate?**

   Yes. Any employee may volunteer during off-duty time or on leave. Medical Center leaders and supervisors must be careful not to encourage or promote participation to avoid any perception of undue influence. If Medical Center leaders decide to join a study, their participation should not be used as a promotion for study recruitment though it can be stated that leaders have chosen to volunteer as to not give the impression that the study is too risky in which to participate.

5. **Can contractors participate in the research studies?**

   No. Contractors are not considered VA employees. A **VA employee** is any individual who is employed by VA, including one who is salaried by VA or is working under a VA Without-Compensation Appointment (38 U.S.C. § 513, 38 U.S.C. § 7405(a)(1), and 38 U.S.C. § 7406) or under an Intergovernmental Personnel Act assignment (5 U.S.C. §§ 3371-75).

6. **Are there additional requirements for the research study team if a potential subject does not have a VHA medical record?**

   Yes. If the study involves a clinical visit, coordination with the VHA medical center medical services office is required to create a medical record in CPRS/CERNER. Study records can only be created by trained personnel. Coordination for support from medical services should be made by the study team prior to the start of study recruitment. Medical Services can train additional staff to augment the study teams during peak enrollment. All participants having a medical record created must also be given a copy (hardcopy or electronic) of the VHA Notice of Privacy Practices. Notice of Privacy Practices

7. **If getting the flu shot is required for a position, but the flu shot will interfere with study participation, may an employee miss a required vaccination with the flu shot?**

   No. There can be no changes in conditions of employment as a result of participation in the research study. All employees who are expected to receive the flu shot by a certain date must have the flu shot by that date. If participation in the study will interfere with that schedule, then the flu shot, or any other employment related examination or treatment, takes precedence.

8. **If an employee takes part in a COVID-19 vaccination trial, will there to be any changes in Personnel Protective Equipment or social distancing requirements?**

   No. There is no intention for an employee to be unnecessarily exposed to the SARS CoV-2 virus as part of these studies. Every precaution that employees have been taking should be continued throughout the study until medical center/VHA guidance is changed for everyone.

9. **If an employee gets sick/harmed from being in a trial and misses work, will the employee be charged leave?**

   Yes. Any time off work will be subject to standard leave policies. Supervisors will not be aware of who is participating in the research trials unless the employee discloses that information.

10. **If a VA employee who is asymptomatic and, in being screened for a research study, is found to have the SARS-CoV-2 virus, what happens?**

    The study team is required to report all positive cases to the VHA medical center leadership and/or local public health authority and follow local VHA policy. The OPM published guidance, "Federal Employee Coverage under the Leave Provisions of the Families First Coronavirus Response Act (FFCRA)" will apply. FFCRA.pdf

11. **If an employee is injured in a COVID-19 study as a result of a countermeasure (vaccine or other therapeutic) and suffers from lost wages, what can the employee do?**

    The DHHS Health Resources & Services Administration has established the Countermeasures Injury Compensation Program (CICP). An injured or harmed study subject may apply for benefits through this program. CICP

12. **If a VA employee wants to participate in a COVID-19 research study and his/her VHA facility is not offering the trial, can the employee participate in a trial through an affiliate or other research organization?**

    Yes. Employment by the VA is not prohibitive for volunteering for research conducted outside of the VHA. All COVID-19 clinical trials can be found at clinicaltrials.gov . To register with the COVID-19 Prevention Network to find a vaccine trial outside of VHA, visit: CoVPN Registry.