INFORMATION PAPER

Military Vaccine Agency
05 June 2008

SUBJECT: Prospective Safety Surveillance Study of Newly Licensed Smallpox Vaccine

1. Purpose. To describe the objectives and design of the prospective safety study.

2. Facts.

a. Background. ACAM2000™ is a live vaccinia virus vaccine recently approved by the U.S. Food and Drug Administration (FDA) for protection against the smallpox virus. It is similar to Dryvax smallpox vaccine previously used by the military, but because it is a new vaccine the manufacturer is required to conduct studies to better understand its safety profile. The major component is a prospective safety surveillance study to gather information concerning expected and unexpected adverse events.

b. Study Objective. The primary objective of this safety surveillance study is to compare the occurrence of myo/pericarditis in Service members who receive ACAM2000™ vaccine to those not receiving smallpox vaccinations.

c. DoD's Role. The DoD is the largest user of smallpox vaccine and has a vested interest in ensuring that it continues to be available for protecting military personnel serving in high risk areas. DoD is combining efforts with the vaccine manufacturer to conduct the study. The Assistant Secretary of Defense for Health Affairs has asked the Naval Health Research Center to conduct the study with support from the Military Vaccine Agency.

d. Study Population. The study cohort includes individuals on active duty processing through Soldier Readiness Programs (SRP) or Battalion Aid Stations (BAS) in preparation for deployment to a high threat area. The research team will enroll 15,000 ACAM2000™ vaccinees and 5,000 controls who were previously vaccinated with a vaccinia vaccine within 6 months to 5 years of study enrollment. The sample size is based on the estimated occurrence of myo/pericarditis.

e. Study Methods. Subjects will be asked to consent to participate in the study at an initial screening visit that occurs with their medical readiness processing. Participants will be instructed to return in 6-17 days from first visit for a single blood draw that coincides with the window to have their vaccination site checked by the local staff. Individuals with positive blood tests for troponin will be referred to a local healthcare provider for follow-up. Those with positive blood tests will be followed by the DoD's Vaccine Healthcare Center to determine the natural history of this finding, as requested by the FDA.

f. Site Role. The study team is independent of site staff and no site staff or medical resources are required for the conduct of the study. The research team will need to be part of the medical readiness process in order to enroll subjects and schedule follow-up visits.

3. Point of contact is Mary Abuja, Naval Health Research Center, 619-553-7628 and LTC Patrick Garman, Military Vaccine Agency, 703-681-5101.

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