Botulinum Neurotoxin Vaccination Information:

The 5th Edition of the Biosafety in Microbiologic and Biomedical Laboratories (BMBL) reports availability of a pentavalent (A, B, C, D and E) botulinum toxoid vaccine (PBT) that is available through the CDC as an Investigational New Drug (IND). Details regarding PBT are available in the IND protocol: Use of Pentavalent (ABCDE) Botulinum Toxoid Aluminum Phosphate Absorbed (PBT) for Workers at Risk of Occupational Exposure to Botulinum Toxins, BB-IND 161, Protocol CDC IRB#392, Version 8.0 [http:// www-ehs.ucsd.edu/bio/pdf/PBT_Protocol_v8_Oct2009.pdf]

Vaccination is expected to result in antitoxin levels that provide potential protection against serotypes of botulinim toxin covered by the vaccine. However, the vaccine was manufactured in the 1970's and recent annual testing showed the vaccine might not work as well as it has in the past against all strains of botulism toxin. It is possible that these results may have been due to problems in doing the testing because these types of tests are hard to do. Since there is a possible decline in vaccine efficacy, this vaccine should not be considered as the sole means of protection and should not replace other worker safety and protection measures. At this time there is no known medical alternative to taking this vaccine that affords the same potential protection from botulism. An unprotected individual involved in a serious exposure to botulism may be given equine botulinum antitoxin after such as exposure; however, supplies of this antitoxin are extremely limited.

Based on over 35 years of vaccine administration experience by CDC under BB-IND 161, PBT appears to have an acceptable safety profile. Reactions were generally mild and consisted of soreness, fever, tiredness, headache, rashes, and muscle pain. Rarely an individual may have a reaction characterized by a deep, painless, non-inflammatory subcutaneous induration that may persist for 3-4 weeks.

The BMBL recommends vaccination for all personnel working in direct contact with cultures of neurotoxin-producing Clostridia species or stock solutions of Botulinum neurotoxin. Due to a possible decline in the immunogenicity of available PBT stocks for some toxin serotypes, the immunization schedule for the PBT recently has been modified to require injections at 0, 2, 12, and 24 weeks, followed by a booster at 12 months and annual boosters thereafter.

The UCSD Center for Occupational and Environmental Medicine and the Institutional Biosafety Committee (IBC) do not recommend vaccination unless a risk-benefit assessment and medical consult is completed. Research staff interested in receiving the vaccination or additional information should contact EHS/Occupational Health at 858-534-8225 to receive assessment and medical consult.