

June 17, 2002

University of Pittsburgh
Addendum to Botulinum Toxoid Consent Form

Name: _____ Social Security/Pitt ID# _____

Clostridium botulinum (*C. botulinum*) is a bacterium, which produces a neurotoxin that causes botulism, a rare but potentially serious paralytic disease. Botulism occurs following the absorption of botulinum toxin into the systemic circulation. It does not go through intact skin. Classically, botulism is a food borne disease however you have been identified as a University employee with potential exposure to botulinum toxin.

With botulism, the rapidity of symptom onset as well as severity of symptoms are influenced by the rate and amount of toxin that enter the circulation. Symptoms include weakness and vertigo that may progress to blurred or double vision, increasing difficulty with speaking and breathing and full involvement of the diaphragm and chest muscles can lead to respiratory failure and death. Passive immunization with equine botulinum antitoxin, which has neutralizing antibodies to toxins A, B, E, may be used to minimize additional nerve injury and disease severity, however it will not undo existing paralysis.

The prevention of botulism can occur through botulinum toxoid. The current pentavalent (ABCDE) botulinum toxoid is an investigational agent that has been provided for over 30 years. The University of Pittsburgh recommends that individuals who handle or manipulate botulinum toxin in the research setting receive the botulinum toxoid vaccine. It is recognized that botulinum toxin has been increasingly utilized for medicinal and cosmetic purposes. Being vaccinated with the botulinum toxoid will prevent botulism, which can be a severe and life-threatening illness, however, accepting vaccination may prevent the effectiveness of any future application of botulinum toxin.

I have been offered at no charge the Pentavalent (ABCDE) Botulinum Toxoid Vaccine, an Investigational New Drug (IND) distributed by the Centers for Disease Control and Prevention (CDC) and administered by Work Partners, Employee health Services, to protect myself from an accidental laboratory acquired infection with Botulism (Botulinum) neurotoxin.

ACCEPT

The risks and benefits of receiving the vaccine and the risks of acquiring botulism from a work exposure have been explained to me. I acknowledge that no guarantees have been made to me regarding the effectiveness of the vaccine or the absence of adverse reactions to the vaccine. I understand this information and have had all of my questions answered. I voluntarily give my consent to receive the Botulinum Toxoid vaccine.

Signature

Date

DECLINE

I understand that due to my occupational exposure to *Clostridium botulinum* (*C. botulinum*) I may be at risk of acquiring botulism. I have been given the opportunity to be vaccinated at no charge to myself. However, I decline the botulinum toxoid vaccination at this time. I understand that by declining this vaccine, I continue to be at risk of botulism.

Signature

Date

Botulinum Toxoid
Consent Form (continued)

PRIOR PENTAVALENT (ABCDE) BOTULINUM TOXOID VACCINE

(Complete if applicable; documentation must be provided)

Name: _____ Social Security/Pitt ID# _____

I have previously received the botulinum toxoid vaccination _____ (*indicate year received*).

By _____ (*indicate doctor/clinic*).

Signature

Date

FOR CLINIC USE ONLY

Date Administered		
Vaccine Manufacturer		
Lot Number		
Expiration Date		
Injection site		
Signature		Date