HEPATITIS B VACCINE DISCLOSURE FORM

Hepatitis B - The Disease
Hepatitis B is a viral infection caused by Hepatitis B virus (HBV) which causes death in 1-2% of patients. Most people with Hepatitis B recover completely, but approximately 5-10% become chronic carriers of the virus. Most of these people have no symptoms, but can continue to transmit the disease to others. Some may develop chronic active Hepatitis and cirrhosis. HBV also appears to be a causative factor in the development of liver cancer. Thus, immunization against Hepatitis B can prevent acute Hepatitis and also reduce sickness and death from chronic active Hepatitis, cirrhosis, and liver cancer.

The Vaccine
Hepatitis B vaccine is produced from recombinant cultures and is therefore free from association with human blood or blood products. It has been extensively tested for safety and efficacy in large scale clinical trials with human subjects. A high percentage of healthy people who receive two doses of vaccine and booster achieve high levels of surface antibody (anti-HBs) and protection against Hepatitis B. Persons with immune-system abnormalities, such as dialysis patients, have less response to the vaccine, but over half of those receiving it do develop antibodies. Full immunization requires three doses of vaccine over a six-month period although some persons may not develop immunity even after three doses. There is no evidence that the vaccine has ever caused Hepatitis B. However, persons who have been infected with HBV prior to receiving the vaccine may go on to develop clinical Hepatitis in spite of immunization. The need for booster doses will continue to be assessed, but is not recommended for adults with normal immune status at this time.

Vaccine Side Effects
Injection site soreness is the primary reaction. Also included are redness, swelling, warmth and hardness of the injection site, all of which subside within 48 hours. Occasionally low grade fever (less than 101.2) will occur which subsides within 48 hours. Systematic complaints include malaise, fatigue, headache, nausea, dizziness, muscle and joint pain - they are infrequent and limited. Rash is rare.
**Indications for Receiving the Vaccine**

People working in the health care field are at higher risk of being infected with Hepatitis B than most other segments of the population because of their contact with infected blood products. Risk of infection increases with frequency of contact with blood. Infection may occur when Hepatitis B virus, transmitted by infected body fluids, contacts mucous surfaces or is introduced through accidental breaks in the skin. Those health care workers at highest risk (according to the Center for Disease Control) are dialysis nurses, lab personnel (particular blood bank and phlebotomist personnel), followed by operating room staff, IV therapy personnel, emergency room and intensive care unit nurses. Other health care workers are at varied risk according to their contact with blood. The American Hospital Association lists those at moderate risk as "those who have some exposure to infected blood, but with only occasional, generally accidental risk of percutaneous inoculation, such as housekeeping and central supply personnel and nonsurgical house staff."

**Contraindication**

Vaccine should be administered with caution to individuals who have exhibited previous systemic allergic reactions to the vaccine or any of the ingredients in the formulation. Administer with caution to individuals with severe cardio-pulmonary status. Vaccination should be delayed in any individual with serious active infections unless withholding the vaccine is considered a greater risk. On the basis of limited experience, there is not apparent risk of adverse effects to developing fetuses when Hepatitis B vaccine is administered to pregnant women (CDC, unpublished data). The vaccine contains noninfectious HbsAg particles and should cause no risk to the fetus. HBV infection affecting a pregnant woman may result in severe disease for the mother and chronic infection for the newborn. Therefore, neither pregnancy nor lactation should be considered a contraindication to vaccination of women. However, pregnant and nursing mothers are advised to seek counsel from their personal physician before taking the vaccine.

**Other Hepatitis Diseases**

This Hepatitis B vaccine does **not** prevent Hepatitis caused by other agents such as Hepatitis A virus, non-A, non-B Hepatitis viruses, or other viruses known to infect the liver. Treat **all** blood and body fluids as potentially infectious.