VACCINE INFORMATION STATEMENT

Hepatitis B Vaccine
What You Need to Know

1 What is hepatitis B?
Hepatitis B is a serious infection that affects the liver. It is caused by the hepatitis B virus.
- In 2009, about 38,000 people became infected with hepatitis B.
- Each year about 2,000 to 4,000 people die in the United States from cirrhosis or liver cancer caused by hepatitis B.

Hepatitis B can cause:
Acute (short-term) illness. This can lead to:
- loss of appetite
- diarrhea and vomiting
- tiredness
- jaundice (yellow skin or eyes)
- pain in muscles, joints, and stomach

Acute illness, with symptoms, is more common among adults. Children who become infected usually do not have symptoms.

Chronic (long-term) infection. Some people go on to develop chronic hepatitis B infection. Most of them do not have symptoms, but the infection is still very serious, and can lead to:
- liver damage (cirrhosis)
- liver cancer
- death

Chronic infection is more common among infants and children than among adults. People who are chronically infected can spread hepatitis B virus to others, even if they don't look or feel sick. Up to 1.4 million people in the United States may have chronic hepatitis B infection.

Hepatitis B virus is easily spread through contact with the blood or other body fluids of an infected person.
People can also be infected from contact with a contaminated object, where the virus can live for up to 7 days.
- A baby whose mother is infected can be infected at birth;
- Children, adolescents, and adults can become infected by:
  - contact with blood and body fluids through breaks in the skin such as bites, cuts, or sores;
  - contact with objects that have blood or body fluids on them such as toothbrushes, razors, or monitoring and treatment devices for diabetes;
  - having unprotected sex with an infected person;
  - sharing needles when injecting drugs;
  - being stuck with a used needle.

2 Hepatitis B vaccine: Why get vaccinated?
Hepatitis B vaccine can prevent hepatitis B, and the serious consequences of hepatitis B infection, including liver cancer and cirrhosis.

Hepatitis B vaccine may be given by itself or in the same shot with other vaccines.

Routine hepatitis B vaccination was recommended for some U.S. adults and children beginning in 1982, and for all children in 1991. Since 1990, new hepatitis B infections among children and adolescents have dropped by more than 95% — and by 75% in other age groups.

Vaccination gives long-term protection from hepatitis B infection, possibly lifelong.

3 Who should get hepatitis B vaccine and when?
Children and Adolescents
- Babies normally get 3 doses of hepatitis B vaccine:
  1st Dose: Birth
  2nd Dose: 1-2 months of age
  3rd Dose: 6-18 months of age

Some babies might get 4 doses, for example, if a combination vaccine containing hepatitis B is used. (This is a single shot containing several vaccines.) The extra dose is not harmful.
- Anyone through 18 years of age who didn't get the vaccine when they were younger should also be vaccinated.

Adults
- All unvaccinated adults at risk for hepatitis B infection should be vaccinated. This includes:
  - sex partners of people infected with hepatitis B,
  - men who have sex with men,
  - people who inject street drugs,
  - people with more than one sex partner,
  - people with chronic liver or kidney disease,
  - people under 60 years of age with diabetes,
  - people with jobs that expose them to human blood or other body fluids,
- household contacts of people infected with hepatitis B, 
- residents and staff in institutions for the developmentally disabled, 
- kidney dialysis patients, 
- people who travel to countries where hepatitis B is common, 
- people with HIV infection.

• Other people may be encouraged by their doctor to get hepatitis B vaccine; for example, adults 60 and older with diabetes. Anyone else who wants to be protected from hepatitis B infection may get the vaccine.

• Pregnant women who are at risk for one of the reasons stated above should be vaccinated. Other pregnant women who want protection may be vaccinated.

Adults getting hepatitis B vaccine should get 3 doses — with the second dose given 4 weeks after the first and the third dose 5 months after the second. Your doctor can tell you about other dosing schedules that might be used in certain circumstances.

4 Who should not get hepatitis B vaccine?

• Anyone with a life-threatening allergy to yeast, or to any other component of the vaccine, should not get hepatitis B vaccine. Tell your doctor if you have any severe allergies.

• Anyone who has had a life-threatening allergic reaction to a previous dose of hepatitis B vaccine should not get another dose.

• Anyone who is moderately or severely ill when a dose of vaccine is scheduled should probably wait until they recover before getting the vaccine.

Your doctor can give you more information about these precautions.

Note: You might be asked to wait 28 days before donating blood after getting hepatitis B vaccine. This is because the screening test could mistake vaccine in the bloodstream (which is not infectious) for hepatitis B infection.

5 What are the risks from hepatitis B vaccine?

Hepatitis B is a very safe vaccine. Most people do not have any problems with it. The vaccine contains non-infectious material, and cannot cause hepatitis B infection. Some mild problems have been reported:

• Soreness where the shot was given (up to about 1 person in 4).
• Temperature of 99.9°F or higher (up to about 1 person in 15).

Severe problems are extremely rare. Severe allergic reactions are believed to occur about once in 1.1 million doses.

A vaccine, like any medicine, could cause a serious reaction. But the risk of a vaccine causing serious harm, or death, is extremely small. More than 100 million people in the United States have been vaccinated with hepatitis B vaccine.

6 What if there is a moderate or severe reaction?

What should I look for?

• Any unusual condition, such as a high fever or unusual behavior. Signs of a serious allergic reaction can include difficulty breathing, hoarseness or wheezing, hives, paleness, weakness, a fast heart beat or dizziness.

What should I do?

• Call a doctor, or get the person to a doctor right away.
• Tell your doctor what happened, the date and time it happened, and when the vaccination was given.
• Ask your doctor, nurse, or health department to report the reaction by filing a Vaccine Adverse Event Reporting System (VAERS) form. Or you can file this report through the VAERS web site at www.vaers.hhs.gov, or by calling 1-800-822-7967.

VAERS does not provide medical advice.

7 The National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program (VICP) was created in 1986.

Persons who believe they may have been injured by a vaccine can learn about the program and about filing a claim by calling 1-800-338-2382 or visiting the VICP website at www.hrsa.gov/vaccinecompensation.

8 How can I learn more?

• Ask your doctor. They can give you the vaccine package insert or suggest other sources of information.
• Call your local or state health department.
• Contact the Centers for Disease Control and Prevention (CDC):
  - Call 1-800-232-4636 (1-800-CDC-INFO) or
  - Visit CDC’s website at www.cdc.gov/vaccines

Vaccine Information Statement (Interim)

Hepatitis B Vaccine

2/2/2012

42 U.S.C. § 300aa-26
**Hepatitis B Consent Form**

**INJECTION # ____________**

**Education:**
- Hepatitis B is a viral infection caused by Hepatitis B Virus (HBV). Approximately 300,000 persons are infected each year in the U.S. A small percentage of these infected persons may become chronic carriers of HBV or develop chronic active hepatitis and/or cirrhosis. There may also be a connection between HBV carrier state and the risk of liver cancer.

- HBV is spread mainly through contact with infected blood or body fluids. Inactivated Hepatitis B vaccine is available in a series of three injections given over a six-month period. Greater than 90% of healthy adults developed protection against HBV after the series. The duration of protection and subsequent need for booster doses has not been identified. There is no evidence that the vaccine ever caused Hepatitis B, but persons who have been infected with HBV prior to immunization may develop clinical hepatitis despite vaccination. The vaccines are a noninfectious subunit vaccine derived from hepatitis B surface antigen produced from yeast cells that are free of association with human blood or blood products.

**Reactions:**
- The most common adverse reaction is pain at the injections site.
- Mild complaints such as fatigue, headache, irritability, or low-grade fever have been reported.
- Serious adverse events and allergic reactions are rarely reported.

**Contraindications:**
- Any person having a prior reaction or sensitivity to the hepatitis B vaccine components or **allergy to yeast**.
- Should not be given to pregnant women or nursing mothers unless strongly indicated.

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**DOB** ____________________________  **Phone:** ____________________________

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Nurse signature: ____________________________

I have received & read the Vaccine Information Sheet dated **2/2/12**. I have been allowed to asked questions. I choose to receive the vaccine today.

Signature ____________________________  **Date:** ____________________________