



APPENDIX 402. CONSENT FORM

SUBJECT INFORMATION PAMPHLET

Introduction:

Diphtheria, tetanus and whooping cough (pertussis) are common infectious diseases prevalent in developing countries. In India according to the WHO the reported cases of Diphtheria, Tetanus and Pertussis in the year 2004 were 8260, 3'318 and 31'511 respectively. DTP vaccine has been used for routine administration to infants for over 50 years and it is also included in expanded programme for immunization (EPI). Hepatitis B continues to be one of the most serious infectious diseases. India has a four percent carrier rate, with 2.5 lakh infants getting infected with HBV every year. The World Health Organization (WHO) recommended the inclusion of hepatitis-B into the EPI in 1991

The Scientific Advisory Group of Experts (SAGE) of the WHO's global program on vaccination recently recognized that combination vaccines is the future of immunization.

The benefits of combination vaccines are:

- (i) Reduced number of injections to children,
- (ii) Reduction in overall cost of vaccination,
- (iii) Increased parent acceptability,
- (iv) Simplified delivery logistics.

Combining hepatitis B vaccine with a vaccine that is included in the WHO-EPI, such as diphtheria, tetanus, and B. pertussis, would facilitate efforts toward reduction of all these four infections.

In ongoing efforts to reduce the global burden of Diphtheria, tetanus and whooping cough (pertussis) and hepatitis B infection, a clinical trial for research purpose is hereby undertaken to evaluate the immunogenicity and safety of a newly developed combination vaccine.

Purpose of Study:

This study entitled "An open label, multicentric study for the evaluation of immunogenicity and safety of _____ (DTPw-Hb combination vaccine) in infants" is a post marketing study (research project) of _____. _____ is a DTPw-Hb Combination Vaccine and the study is being done for evaluation of immunogenicity and safety of vaccine, developed by _____.

Qualification to Participate:

During the first visit the Doctor will evaluate the subject (child). If your child fulfils all the criteria to participate in the trial he/ she will be enrolled in the study.

Study Procedure:

After enrolment in the study the child will receive three doses of DTPw-HB over a period of 8 weeks. Before administration of the vaccine a blood sample (1.5ml) will be taken to analyze presence of antibodies. Another blood sample will be taken three to six weeks after the third dose of the vaccine.

You will agree to use drugs only as instructed by the study doctor. You will need to bring the child to the study doctor for evaluation and treatment at least four times over a period of 12 weeks.

Risks:

Any vaccine may have some side effects. The possible side effects with this combination vaccine reported in the scientific publications are –

- (i) Your child may experience pain, discomfort, and redness or swelling at the injection site; however these side effects usually clear up within a few days.
- (ii) Other side effects, which may occur, are fever ($>100.4^{\circ}\text{F}$), drowsiness, irritation, vomiting, loss of appetite and persistent weeping and unusual crying.
- (iii) As with all injectable vaccines there is an extremely small risk of allergic or anaphylactic reactions.

If your child shows any symptoms, you should report them to the investigator immediately.

Indemnity:

Despite following the instructions of the study doctor, if your child suffers from any serious adverse event requiring medical treatment, _____ will pay the medical expenses for the treatment. No other compensation for participating in trial is available from _____.

Possible benefits:

You can receive information about your child's immunity and health status from physical and laboratory tests done in the study. In this study your benefit is that you will get free vaccines and conveyance allowance.

Alternative Procedure:

You can immunize your child with vaccines of different brands available in the market either combination vaccines or individual component vaccines.

Confidentiality:

If you agree to participate in this study, the information obtained will be kept confidential and only competent authorities like the Drug Controller General of India, the Ethics Committee and the members of the study team and the sponsors and/ or its representatives can have direct access to the records.

Right to Withdraw:

You have the right to withdraw your child from the study when you feel like. You will not be asked any reason for your withdrawal and no one will force you to continue your participation.

Signatures:

To enroll your child into this study, you as a legal representative must sign and date the signature page of the consent form.

Client's Instructions:

1. Medical and other agreed terms to be transliterated
2. The abbreviations in brackets have to be maintained in English.