



**IWK Health Centre  
Clinical Trial Information, Consent, and Authorization Form  
April 21, 2009**

**TITLE:** Immunization of Women with Diphtheria and Tetanus Toxoids Combined with Acellular Pertussis (Tdap) During the Mid Third Trimester of Pregnancy: An Evaluation of the Potential for Immunological Protection for the Neonate. (Protocol #003)

**SHORT TITLE:** Maternal Immunization Study

**MEDICAL PRINCIPAL INVESTIGATOR:** Dr. Scott Halperin, Pediatric Infectious Diseases, IWK Health Centre

**PRINCIPAL INVESTIGATOR:** Beth Halperin, RN, MN, Center Manager, CTRC, IWK Health Centre

**CO-INVESTIGATORS:** Dr. Joanne Langley, Pediatric Infectious Diseases, IWK Health Centre  
Dr. Shelly McNeil, Infectious Diseases, QEII Health Sciences Centre  
Dr. Victoria Allen, Dept. of Obstetrics & Gynaecology, IWK Health Centre

**SPONSOR:** Canadian Center for Vaccinology

**Introduction**

We would like to invite you and your baby to take part in the research study named above. This form provides information about the study. Before you decide if you want to take part, it is important that you understand the purpose of the study, the risks and benefits, and what you will be asked to do. You do not have to take part in this study. Taking part is entirely voluntary (your choice). Informed consent starts with the initial contact about the study and continues until the end of the study. A staff member from the research team will be available to answer any questions you have. You may decide not to take part or you may withdraw from the study at any time. This will not affect the care you or your family members will receive from the IWK Health Centre in any way.

### **Why are the researchers doing the study?**

Pertussis is a respiratory infection caused by a bacteria called *Bordetella pertussis*. Pertussis is also known as “whooping cough” because it causes severe spells of coughing followed by a loud gasp or whoop sound before the next breath. It can also cause you to vomit after coughing, to turn blue, and to stop breathing. Complications can include pneumonia (an infection of the lungs), hernia, haemorrhage (bleeding), and brain damage. Young infants are at highest risk of complications, hospitalization, and death. The pertussis vaccine has controlled whooping cough in young children; however, those too young to have completed their immunization series continue to get the disease.

In Canada, there are 1–3 deaths each year from whooping cough; all have been in infants too young to have begun their immunization series. Over the last decade, an increasing number of cases have been reported from adolescents and young adults; these individuals may contribute to the spread of the infection to these highly susceptible infants.

One way of protecting young infants is to improve the protection levels of people in direct close contact with them and thereby reduce the spread of infection. This is called the cocoon strategy and requires the parents to be immunized against pertussis in order to protect their young infant. Another way to protect infants may be through immunizing mothers when they are pregnant. This is routinely done with tetanus vaccine and has been extremely successful in almost eliminating newborn lockjaw around the world.

The purpose of this study is to see if the antibodies (protection) are transferred from mother to baby through the placenta and breast milk in high enough levels to provide protection to the newborn baby if the mother receives the pertussis vaccine during the mid third trimester of pregnancy. We are also looking to see if vaccinating the mother will affect the baby’s protection levels once the baby starts receiving his/her routine baby needles.

### **How will the researchers do the study?**

This study is being done in two phases. In the first phase, 50 healthy pregnant women will take part in the study at the IWK Health Centre. After birth, the baby’s blood work taken until the 7-month visit will be tested to make sure that the baby’s protection levels are as expected. If they are, then an additional 390 women will be enrolled in the study at other sites in Canada. Overall, a total of 440 women and their babies will be participating.

Half of the women will receive a licensed study vaccine called ADACEL<sup>®</sup> (tetanus, diphtheria, and acellular pertussis vaccine) and half will receive a licensed control vaccine called Td ADSORBED (diphtheria and tetanus vaccine) when they are approximately 34 weeks pregnant. You will be randomized (like flipping a coin) to either receive the study vaccine or the control vaccine. Neither you nor the study staff (other than the study nurse giving you the needle) will know which vaccine you received, although this information is available should it be needed. There are two different study groups so we are able to compare the mothers and babies from each group.

Blood and colostrum/breast milk samples (or saliva samples if breast milk samples are not available) will be taken from you to measure the antibody (protection) levels seven times during the study.

We will vaccinate your baby with the routine baby needles at 2, 4, 6, 12, and 13 months of age. Prior to these immunizations, we will take a blood sample from your baby. A blood sample will also be taken 4–6 weeks after the 6 month vaccine and one month after the 12 month vaccine. We will be checking your child's antibody (protection) levels.

To be in the study, you must be healthy and have had an uncomplicated pregnancy. You must not have received a tetanus-diphtheria immunization within the past two years and not have had pertussis (whooping cough) in the past five years.

### **What will I be asked to do?**

Participation in the study involves ten visits including today. The visits can occur at the IWK Health Centre or we can do some of the visits at your home if you prefer. We estimate the total time commitment to participate in the study will be approximately 9-10 hours.

At the first visit, the study information, consent and authorization form will be reviewed with you. If you decide to take part, you will be asked to sign this form and you will receive a copy of it to keep. At other visits, we will briefly review with you the main points about the study to make sure that you want to continue to take part. At visit 1, after the consent form is signed, we will ask you to undergo a fetal ultrasound for the study to check the growth of your baby. Due to scheduling, this may be at a different time than the visit 1. This will be in addition to the ultrasounds you may have as part of your routine care by your doctor.

At the second visit, we will ask you some questions about your health history and we will perform a physical exam. In addition, the study obstetrician will review your ultrasound and do a pregnancy assessment to ensure that you are eligible for the study. On this visit, a baseline blood sample and a saliva sample will be taken. These assessments and samples are in addition to any routine prenatal checkups you will have with your own doctor. A blood sample of 5 mL (about 1 teaspoon) will be taken. The saliva sample involves putting a collecting pad under your tongue for approximately 3–5 minutes. You will be randomized (like flipping a coin) to see which vaccine you will receive. You have an equal chance of receiving either the study vaccine, ADACEL<sup>®</sup> (tetanus, diphtheria, and pertussis vaccine), or the control vaccine, Td (tetanus and diphtheria vaccine). The vaccine will be given in your upper arm. After it is given, there is a 15-minute waiting period to make sure you do not have a rare allergic reaction. You will be given a diary card to record your temperature and any reactions where you got the needle (redness, tenderness, or swelling) for 7 days. We will call you 8 days after the vaccine to collect information from the diary card. Arrangements will be made to see you after you deliver.

Immediately after you deliver, a blood sample of 3–5 mL (about ½–1 teaspoon) will be taken from your baby's umbilical cord after it has been separated from the baby. This is done routinely, and we will ask that an additional tube of blood be taken for the study tests. A blood and colostrum/breast milk sample (or saliva sample if colostrum is unavailable or you are planning not

to breastfeed) will be taken from you within 48 hours after you deliver. To obtain a breast milk sample, we will ask you to express 1 mL (less than ½ teaspoon) of breast milk into a sterile container. The study nurse will explain how to express the breast milk if you are not already aware. The blood test is for the study and is in addition to any blood samples that may be taken after you deliver your baby. Normally, colostrum/breast milk or saliva samples are not obtained.

We will give your baby the routine immunizations (baby needles) at 2, 4, 6, and 12 months of age. Prior to these needles, a blood sample of 3–5 mL (about ½–1 teaspoon) will be taken from your baby from a vein or fingerpoke. EMLA<sup>®</sup> can be applied prior to the test to numb the skin and decrease the pain. The blood will be tested for your child's antibody (protection) levels against the diseases before the immunizations and throughout the study. At these visits, a blood sample and a breast milk (or saliva) sample will be taken from you as well. Samples are not taken from you or your infant routinely.

The booster dose of Prevnar<sup>®</sup> and Pentacel<sup>®</sup>/PediaceL<sup>®</sup> will be given earlier than the routine Nova Scotia schedule of 18 months. Pentacel<sup>®</sup>/PediaceL<sup>®</sup> will be given at 12 months of age along with the other routine 12-month immunizations for measles-mumps-rubella (MMR), varicella (chicken pox) and **Meningococcal C conjugate vaccine**. Prevnar<sup>®</sup> will be given at the 13-month visit.

At 7 months, a blood sample will be taken from your baby. A blood sample and a breast milk (or saliva) sample will be taken from you. The final visit is 4–6 weeks after your baby's 12-month immunization. A blood sample will be taken from your baby at this time.

Your baby's growth measurements (head circumference, length, and weight) will be taken at delivery and done at all other study visits. At 18 months of age, we will evaluate your baby's development with a commonly used test. It takes about under 45 minutes to complete and involves the study staff watching your baby perform certain activities that are considered normal for his or her age. These test results will be provided to you. This 18-month developmental assessment is an additional assessment not routinely done by your family doctor. The study visits do not replace your child's well baby check with your family doctor. **It is important that you see your family doctor at the usual times for assessment. However, your baby will not need any immunizations at those visits.**

At each study visit, we will ask you questions about your health and your child's health. We will be recording information about any doctor, emergency room or hospital visit and any medications taken by you or your child. We will provide a memory aid to remind you to record this information.

During the study, a questionnaire will be given to you to complete. We will ask you to return the questionnaire at the next study visit or you can mail it to us in a pre-addressed stamped envelope that we will provide to you if you wish. We will ask you questions about your knowledge and opinions about immunization in newborns and women prior to, during, and immediately following pregnancy.

### Summary of Scheduled Visits & Procedures

Visit #	1	2		3	4	5	6	7	8	9	10
When	30–32 wks pregnant	34 wks pregnant	8 days after immunization	Delivery day (up to 2 days after delivery)	2 months old	4 months old	6 months old	7 months old (4–6 wks after Visit 6)	12 months old	13 months old (4–6 wks after Visit 8)	18 months old
Details	<ul style="list-style-type: none"> <li>➤ informed consent</li> <li>➤ inclusion/exclusion criteria</li> <li>➤ fetal ultrasound</li> <li>➤ given questionnaire to complete &amp; return</li> </ul>	<ul style="list-style-type: none"> <li>➤ review informed consent</li> <li>➤ review inclusion/exclusion criteria</li> <li>➤ medical history &amp; medications in past 14 days</li> <li>➤ physical exam</li> <li>➤ assessment by study obstetrician</li> <li>➤ blood sample</li> <li>➤ saliva sample</li> <li>➤ randomization: study vaccine or control vaccine</li> <li>➤ 15-minute wait</li> <li>➤ given diary card</li> <li>➤ record any Dr/ER visits &amp; meds</li> <li>➤ arrange to see you when you deliver</li> </ul>	<ul style="list-style-type: none"> <li>➤ telephone call to collect diary card information</li> </ul>	<ul style="list-style-type: none"> <li>➤ review informed consent &amp; interim history</li> <li>➤ cord blood sample (baby immediately after delivery)</li> <li>➤ blood sample (mom)</li> <li>➤ colostrum/breast milk sample (or saliva if breast milk unavailable) within 48 hours of delivery</li> <li>➤ record baby's measurement</li> <li>➤ record any Dr/ER visits &amp; meds (mom)</li> <li>➤ given memory aid</li> </ul>	<ul style="list-style-type: none"> <li>➤ review informed consent &amp; interim history</li> <li>➤ blood sample (mom &amp; baby)</li> <li>➤ breast milk (or saliva) sample (mom)</li> <li>➤ measure baby's growth</li> <li>➤ baby's routine needles (Prenvar® &amp; Pentacel/Pediacel®)</li> <li>➤ 15-minute wait</li> <li>➤ review memory aid &amp; record any Dr/ER visits &amp; meds (mom/baby)</li> </ul>	<ul style="list-style-type: none"> <li>➤ review informed consent &amp; interim history</li> <li>➤ blood sample (mom &amp; baby)</li> <li>➤ breast milk (or saliva) sample (mom)</li> <li>➤ measure baby's growth</li> <li>➤ baby's routine needles (Prenvar® &amp; Pentacel/Pediacel®)</li> <li>➤ 15-minute wait</li> <li>➤ review memory aid &amp; record any Dr/ER visits &amp; meds (mom/baby)</li> </ul>	<ul style="list-style-type: none"> <li>➤ review informed consent &amp; interim history</li> <li>➤ blood sample (mom &amp; baby)</li> <li>➤ breast milk (or saliva) sample (mom)</li> <li>➤ measure baby's growth</li> <li>➤ baby's routine needles (Prenvar® &amp; Pentacel/Pediacel®)</li> <li>➤ 15-minute wait</li> <li>➤ review memory aid &amp; record any Dr/ER visits &amp; meds (mom/baby)</li> </ul>	<ul style="list-style-type: none"> <li>➤ review informed consent &amp; interim history</li> <li>➤ blood sample (mom &amp; baby)</li> <li>➤ breast milk (or saliva) sample (mom)</li> <li>➤ measure baby's growth</li> <li>➤ review memory aid &amp; record any Dr/ER visits &amp; meds (mom/baby)</li> </ul>	<ul style="list-style-type: none"> <li>➤ review informed consent &amp; interim history</li> <li>➤ blood sample (mom &amp; baby)</li> <li>➤ measure baby's growth</li> <li>➤ baby's routine needles (Pentacel/Pediacel®, MMR, Chicken Pox &amp; Meningo-coccal C conjugate vaccine)</li> <li>➤ 15-minute wait</li> <li>➤ review memory aid &amp; record any Dr/ER visits &amp; meds (mom/baby)</li> </ul>	<ul style="list-style-type: none"> <li>➤ review informed consent &amp; interim history</li> <li>➤ blood sample (baby)</li> <li>➤ measure baby's growth</li> <li>➤ baby's routine needles (Prenvar®)</li> <li>➤ review memory aid &amp; record any Dr/ER visits &amp; meds (mom/baby)</li> </ul>	<ul style="list-style-type: none"> <li>➤ review informed consent &amp; interim history</li> <li>➤ measure baby's growth</li> <li>➤ assess baby's development with screening test</li> <li>➤ review memory aid &amp; record any Dr/ER visits &amp; meds (mom/baby)</li> </ul>
Time	2 hours	1 hour	15 minutes	30 minutes	1 hour	1 hour	1 hour	30 minutes	45 minutes	45 minutes	45 minutes

Deleted: SP71 21Apr09ICF.doc

## **What are the burdens, harms, and potential harms?**

The study product, ADACEL<sup>®</sup> (tetanus, diphtheria, and acellular pertussis vaccine), is a licensed vaccine in Canada for use in persons 4–64 years of age. The most common reactions that have been seen are soreness, redness, and swelling at the injection site. Other possible reactions include muscle aches, fever, malaise (fatigue), chills, headache, generalized body ache, tiredness, nausea, vomiting, anorexia (lack of appetite), diarrhea, sore joints, or lymph node swelling. Other less common reactions that have been reported include injection site nodules (lumps) and abscess (infection), itching, allergic reaction (hives), and fainting.

The control product, Td (tetanus and diphtheria vaccine), is a licensed vaccine in Canada for use in people 7 years of age and older. The most common reactions that have been seen are soreness, redness, and swelling at the injection site. Other possible reactions include muscle aches, fever, malaise (fatigue), chills, headache, generalized body ache, tiredness, nausea, vomiting, anorexia (lack of appetite), diarrhea, sore joints, or lymph node swelling.

**We do not know whether giving this vaccine will cause any adverse effects to the unborn baby or how antibodies transferred through the placenta and breast milk will affect your baby's response to receiving his/her immunizations.**

The routine infant immunizations in Nova Scotia are Prevnar<sup>®</sup>, Pentacel<sup>®</sup>/PediaceL<sup>®</sup>, **Meningococcal C conjugate vaccine**, MMR (measles, mumps, rubella), and varicella (chicken pox). Prevnar<sup>®</sup> protects against 7 different types of pneumococcal infections. Pentacel<sup>®</sup>/PediaceL<sup>®</sup> protects against diphtheria, tetanus, polio, pertussis, and *haemophilus influenzae* type B (HIB). **Meningococcal C conjugate vaccine** protects against the C type of meningococcal disease. The MMR vaccine protects against measles, mumps and rubella. The varicella vaccine protects against chicken pox. Some children may experience minor local or general reactions from these vaccinations, including soreness, redness, and swelling at the site of the needle or general reactions such as mild fever, fussiness, vomiting, drowsiness, poor appetite, or a rash. These symptoms are minor and usually go away without treatment.

**It is possible that babies whose mothers were vaccinated during pregnancy will not have as good a response to their usual baby needles as babies whose mothers were not vaccinated. We will be measuring your baby's antibody levels throughout the study to make sure that s/he has adequate protection and immunity against diphtheria, pertussis (whooping cough), tetanus and *haemophilus influenzae* type b (Hib). In addition, we will administer the booster dose of Pentacel<sup>®</sup>/PediaceL<sup>®</sup> early at 12 months rather than at 18 months to ensure that your baby has the best possible protection against these diseases.**

As with any vaccine or drug, you or your child could experience a rare allergic reaction or have reactions that have not been seen before. Study staff are trained and equipped to deal with such reactions should they occur. If either of these happens, one of the study doctors will see you or your child and give immediate advice about any medical treatment.

The blood tests done on you and your infant can cause momentary pain and rarely a bruise. A patch called EMLA<sup>®</sup> that numbs the skin can be used if you like. Blood tests can sometimes cause

Deleted: SP71 21Apr09ICF.doc

lightheadedness and rarely fainting or infection at the site where the test was done. The cord blood test does not cause pain because it is done after the umbilical cord has been separated from the baby.

### **What are the possible benefits?**

If you receive the study vaccine, you will receive protection against diphtheria, tetanus, and pertussis (whooping cough). If you receive the control vaccine, you will receive protection against diphtheria and tetanus. It is recommended that adults receive a diphtheria and tetanus booster every 10 years to maintain adequate protection. As previously mentioned, adults who are protected against pertussis may be able to protect young children by protecting themselves through the cocoon strategy. Mothers may also provide protection against pertussis to their newborn through antibodies in their breast milk and placenta.

The blood samples collected in this study will be tested for the protection levels against diphtheria, tetanus, and pertussis for you and diphtheria, tetanus, pertussis and *haemophilus influenzae* type b (Hib) your child. If you or your child has not reached what is felt to be a protective level, you will be contacted by study staff and a booster dose will be offered to you or your child.

By participating in this study we may gain information that will help us design future studies to determine ways to protect infants against pertussis.

### **What alternatives to participation do I have?**

You and your baby do not have to participate in this study. The tetanus and diphtheria booster is available free of charge from your family doctor and the vaccine that contains tetanus, diphtheria, and pertussis can be purchased. These vaccines typically would not be provided during pregnancy. The routine baby needles are available from your family doctor. There are no blood tests required when receiving vaccines through your family doctor.

### **Can I withdraw from the study?**

Taking part in this study is entirely voluntary (your choice). If you decide to enroll and later change your mind, you are free to withdraw at any time. Withdrawing will not cause any risk to you or your baby and will not affect your care by your doctor or the IWK Health Centre. If you choose to withdraw from the study, notify your study nurse of your wishes. Study staff will contact your family doctor to recommend what additional vaccines your child will need to receive complete protection.

If you decide to withdraw partway through the study any data collected until that time will not be removed. If the study is changed in any way that would affect your decision to continue to participate you will be told about the changes in a timely manner and may be asked to sign a new consent form.

Your or your child's participation could be ended if, in the investigator's clinical judgment, it is in your best interest not to continue or you are unable to complete the study requirements. You will

Deleted: SP71 21Apr09ICF.doc

be notified by study staff if this should occur and given information regarding how to contact study staff if you have any questions after you are withdrawn from the study.

**Will the study cost me anything and, if so, how will I be reimbursed?**

There will be no costs to you to take part in the study. In recognition of your time commitment to the study and transportation costs, you will receive \$25 for the individual visits and \$50 for the visits with you and your baby (\$400 in total). If for any reason you do not complete the study, you will be compensated for the total number of visits completed up to that time. You will receive a cheque (\$250) approximately 4 weeks after the 7-month visit and the rest (\$150) 4 weeks after the final visit. You will be asked to sign a form to receive the cheque.

**Are there any conflicts of interest?**

There are no known conflicts of interest on the part of the researchers and/or the IWK Health Centre. The Sponsor will cover the costs of operating the study at the IWK Health Centre and the study nurses and doctors will not be paid extra money to work on the study.

**What about possible profit from commercialization of the study results?**

If the study results indicate a change in licensing recommendations after the study is completed, you will not receive any of the financial benefits.

**How will I be informed of the study results?**

The overall study results and your child's and your individual protection levels can be made available to you once the study is completed and reported. For the first 50 infants, blood will be tested after the 7-month visit is completed and you will be notified if your child needs a booster. The results will be mailed to you if you want to receive them. You will be asked to initial the last page of this page of this form indicating if you wish to receive the results.

**How will my privacy be protected?**

Any information that is learned about you will be kept private. Study staff will have access to your study and medical records including your prenatal blood and ultrasound results and information about your infant's delivery and if s/he is hospitalized. In addition, the records may be shown to representatives of the Sponsor, the Research Services office of the IWK Health Centre, and the federal regulatory authorities in Canada and the United States. By signing this form, you are allowing this access. If the results of the study are published in the medical literature, the publication will not contain any information which would identify you. Study records will be stored in a locked area and will be kept for 10 years past the age of majority for the infant (i.e., 29 years) as required by Health Canada. Documentation of your baby's and your study participation, receipt of the vaccine, and the study results will be forwarded to your family doctor for your chart. A record of the immunizations will also be sent to public health.

Deleted: SP71 21Apr09ICF.doc

**What are my research rights?**

If you or your baby become ill or injured as a direct result of participating in this study, necessary medical treatment will be available at no additional cost to you. Your signature on this form only indicates that you have understood to your satisfaction the information regarding your participation in the research study and agree to participate as a subject. In no way does this waive your legal rights or release the investigators, the study sponsor, or involved institutions from their legal and professional responsibilities.

If you have any questions at any time during or after the study about these rights or about research in general, you may contact the Research Services Office of the IWK Health Centre at 470-8765, Monday to Friday between 9 am and 5 pm.

**Future use of specimens**

As part of the study, blood, saliva, and breast milk samples will be taken to test the protection levels of you and your infant. The tests will be done by the Canadian Center for Vaccinology and sanofi pasteur. The samples will be stored in a freezer until the tests are done. It is standard procedure to maintain the sample for no more than 15 years in case additional testing is required by the regulatory authorities or the sponsor. The samples are identified only by a participant ID number; they do not include your child's or your name. You will not receive direct benefit from retesting of these samples. These samples will not be used for genetic testing.

**Contact for future studies**

You will be asked if you are willing to be contacted for future studies by our staff. This could be for you or any minor children. If you wish to be included, we will collect information needed to contact you/your children in the future. This information would include your name, address, phone number, and dates of birth which we would store in a secure area. If you wish to be contacted, we will ask you to initial the signature page of this form to indicate this. We will not collect this information until the final study visit when we will reconfirm that you still wish to do this. If you indicate you agree today and then change your mind later, that is not a problem and will not impact your care in any way.

**What if I have study questions or problems?**

Your study nurse carries a pager at all times. Her name is \_\_\_\_\_. If you have any questions or concerns during the study, you may call the study nurse at \_\_\_\_\_ and leave a message. You may also call the Research Coordinator, Pam MacIntyre, Monday to Friday between the hours of 9 am and 5 pm at 470-8948. In an emergency, you may also reach the study nurse, Patricia Smith, or Dr. Halperin at any time of the day or night by calling the IWK Health Centre at 470-8888 and asking for them to be paged. If you cannot reach them quickly by pager for any reason, you should see your family physician or go to the Emergency Department. In the event that participation in this study has led to any reactions or serious events, please contact your study nurse or) as soon as possible. The matter will be reviewed with you and Dr. Halperin, who will help you get appropriate medical care.

Deleted: (name to be inserted)

Deleted: (name to be inserted)

Deleted: )

Deleted: (name to be inserted)

Deleted: SP71 21Apr09ICF.doc

**Study Title:** Immunization of Women with Diphtheria and Tetanus Toxoids Combined with Acellular Pertussis (Tdap) During the Mid Third Trimester of Pregnancy: An Evaluation of the Potential for Immunological Protection for the Neonate. April 21, 2009.

**Participant ID:** \_\_\_\_\_ **Participant Initials:** \_\_\_\_\_

**Participant Consent & Authorization:** I have read or had read to me this information, consent and authorization form and have had the chance to ask questions which have been answered to my satisfaction before signing my name. I understand the nature of the study and I understand the potential risks. I understand that I have the right to withdraw myself or my child from the study at any time without affecting our care in any way. I have received a copy of the Information, Consent & Authorization Form for future reference. I freely agree to participate and have my child participant in this research study.

\_\_\_\_\_  
Name of Participant (Print) Signature of Participant

Date: \_\_\_\_\_ Time: \_\_\_\_\_

I would like to receive a copy of the study results when available. Yes or No: \_\_\_\_\_ (initial)

I agree to be contacted and given information about future studies. Yes or No: \_\_\_\_\_ (initial)

**STATEMENT BY PERSON PROVIDING INFORMATION ON THE STUDY**

I have explained the nature and demands of the research study and judge that the participant named above understands the nature and demands of the study.

Name (print): \_\_\_\_\_ Position: \_\_\_\_\_

Signature: \_\_\_\_\_ Date: \_\_\_\_\_ Time: \_\_\_\_\_

**STATEMENT BY PERSON OBTAINING CONSENT**

I have explained the nature of the consent process to the participant and judge that they understand that participation is voluntary and that they may withdraw at any time.

Name (print): \_\_\_\_\_ Position: \_\_\_\_\_

Signature: \_\_\_\_\_ Date: \_\_\_\_\_ Time: \_\_\_\_\_

This study is funded by sanofi pasteur. The vaccine manufacturer has supplied the funds necessary to conduct this research. However, the study protocol has been designed and written by the above-named investigators. The IWK Health Centre and Dalhousie University assume all responsibility and liability for this study. As well, all information obtained from the conduct of this study is owned by the investigators and is not the property of sanofi pasteur.

Deleted: SP71 21Apr09ICF.doc