Approved: 11Nov2016

INFORMED CONSENT AND HIPAA AUTHORIZATION FORM FOR SUBJECT PARTICIPATION IN A RESEARCH STUDY: OPTIONAL BIOLOGICAL SAMPLES

Name of Research Study: A Phase 2b Randomized, Double-blind, Placebo-controlled Study to Evaluate the Safety and Efficacy of MEDI8897, a Monoclonal Antibody With an Extended Half-life Against Respiratory Syncytial Virus, in Healthy Preterm Infants

Study Code/Protocol Number: D5290C00003

Sponsor: MedImmune, LLC

Study Doctor Name: **Alejandro Hoberman**

Institution: **UPMC**

Research Site Address(es):

General Academic Pediatrics
Children's Hospital of Pittsburgh
3414 Fifth Ave
Pittsburgh PA 15213

Daytime Telephone Number(s): 412-692-7382

24-hour Contact Number(s): 412-999-EARS (3277)

Subject Initials: _____

Enrolment Code: _____

This is an extra Informed Consent form. It is separate from the main consent form that you signed. This extra Informed Consent Form does not repeat information in the Informed Consent for the Main Study and it does rely on the HIPAA Authorization of that Main Study consent form. It asks for your consent to perform further research on blood or nasal samples taken from your child during the main study. It also asks for your consent to be contacted after the study has completed to answer questions regarding your child's health related to respiratory illness and wheezing. You do not have to agree for your child to take part in any of this additional research to take part in the main study. Please read this information carefully and discuss any questions you may have with your child's study doctor.

If you do not understand any words or phrases in this form, look back at the form for the main study or ask your study doctor.

The Sponsor (MedImmune) wants your permission to perform additional research, outside of that described in the main study consent form and HIPAA Authorization, either now or in the future, on blood or nasal samples that you have already provided as a part to the main study: blood sample of 1.5 mL (about 1/3 teaspoon) at each of these visits: Visit 1 – Screening, , Visit 4 – Day 91, Visit 5 – Day 151, and Visit 6 – Day 361, and nasal samples collected for medically attended respiratory illnesses.

The Sponsor also wants your permission to be contacted after study completion to answer questions related to your child's health regarding respiratory illness and wheezing. The study doctor or a member of his/her team will contact you for this information. The contact will occur several years after study completion.

PURPOSE OF THIS RESEARCH

The research that may be done with these specimens is not designed to help your child. Reports about this research will not be given to you or the study doctor. These reports will not be put in your child's health record. Your child's specimens will be coded in such a manner that it should not be possible for the researchers using the specimens to find out that they came from your child.

The specific nature of research will vary and is not fully known at this time.

All the testing done on your child's blood or nasal samples, now and in the future, will be performed for research and development purposes only. In addition to the purposes set out in the main Informed Consent Form, this research may also lead to the development of new patents, drugs, or biological products. It is possible that the Sponsor may work with third parties including other companies and with other research institutions to conduct the testing and research, and may share your child's samples and/or data with them in accordance with the main Informed Consent Form and HIIPAA Authorization.

No human genetic research (DNA testing) will be done on these samples.

The information you may provide regarding your child's health after study completion will help to understand respiratory illnesses and wheezing in children. Questions will be specific to respiratory illnesses and any experiences of wheezing your child may have had. No other questions regarding your child's health or health status will be asked. The information will be collected by the study doctor or a member of his/her team.

STORAGE OF BIOLOGICAL SAMPLES

This additional research may not start immediately. Your child's samples will be stored by the Sponsor with similar samples from other people at a secure central laboratory located in the United States. Your child's samples will not be kept for more than 25 years after the end of the study in which they were collected.

CONFIDENTIALITY

You have a right to privacy and all information that is collected for this study will be kept confidential to the limit that this is possible by law. Except as required by law, you will not be identified by name, address, birth date, telephone number, or any other personal identifier.

To help ensure that your medical and personal information is kept confidential, all documentation and samples related to this study will be de-identified. You will be assigned a unique patient identification number. Your forms, records, and samples associated with this study will be labeled with this unique code (or identification number) only. They will not be labeled with your name, picture, or any other personally identifying information.

Only your study team will have access to the key that links your unique code to you. This information will not be released to the sponsor, their affiliates, or anyone outside of the study team except as described in this consent document or where required by law – or as directed by your written request for destructions of your samples from future research.

Request for Destruction of Biological Samples

If you first agree to participate and then you change your mind, you are free to withdraw your consent and discontinue your participation in the study at any time. You also have the right to ask that all retained bio-specimen samples (blood, nasal samples) be destroyed (if they can be identified by study ID or linkage code) to prevent future use or analysis by anyone. To do this, send a written request to withdraw from the study to the person and address listed above. If the samples have been completely de-identified, it will be impossible to destroy them.

WHAT ARE THE ALTERNATIVES?

You may choose to not allow use of your child's samples for this future research.

CAN I WITHDRAW MY CONSENT?

You may withdraw your child's consent to the use of their donated sample(s) or to be contacted to answer respiratory illness and/or wheezing questions at any time by

contacting your study doctor/nurse. If you withdraw your child's consent to the use of the samples and the samples have not been anonymized (link between your child and your child's samples do not exist) the study doctor or the sponsoring company will arrange to have it destroyed and you will be notified of the action.

However, if any analysis has already been performed the Sponsor is not obliged to destroy the results of this research.

DO I RECEIVE A PAYMENT FOR MY CHILD'S TAKING PART?

You will not be paid for having your child's study samples used in future research.

WHAT ARE THE POSSIBLE RISKS AND INCONVENIENCES OF TAKING PART?

No additional samples will be taken from your child for this future research. Therefore, your child's participation will not involve any risk if he/she takes part in this future research.

WHAT IF I AM INJURED AS A DIRECT RESULT OF PARTICIPATING IN THIS STUDY?

There is little risk involved in this study. No invasive procedures or medications are included. The major potential risk is a breach of confidentiality. The study team and the sponsor are bound by both federal and state law to do everything possible to protect your privacy. In signing this form, you do not give up any legal rights.

WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART?

There is no direct benefit to your child. However, this research may contribute to our understanding of the prevention of respiratory diseases.

INFORMED CONSENT STATEMENT

I have received verbal information on this optional research on my child's biological samples and future questions regarding my child's respiratory illness and/or wheezing episodes and have read the written information.

I have been given the chance to discuss this research and ask questions.

I consent to the biological samples, which my child will donate, being used as indicated in the text, and according to the option(s) I have initialed/signed below.

I consent to be contacted at a later date to answer questions related to my child's health regarding respiratory illness and wheezing.

COLLECTION OF SAMPLES AND PURPOSE OF THE RESEARCH

I agree to donate the leftover from the biological sample(s) that I have already provided in the main study, to be tested for the Sponsor to learn more about the functioning and the diseases of the human body in addition to the disease studied in the main study.

☐ Yes ☐ No _____ Initials of Parent/Legal Guardian and Date/Time

QUESTIONS RELATED TO MY CHILD'S HEALTH REGARDING RESPIRATORY ILLNESS AND WHEEZING

I agree to be contacted at a later date after study completion to answer questions related to my child's health regarding respiratory illness and wheezing.

☐ Yes ☐ No _____ Initials of Parent/Legal Guardian and Date/Time

I am aware that my child's participation, sample donation, and answering questions after study completion is entirely voluntary.

I understand that I may, on behalf of my child, withdraw his/her consent at any time without penalty, loss of benefits or this affecting my child's future care.

I understand that I will, on behalf of my child, receive a signed and dated copy of this information and Consent Form.

_____ _____

Signature of Parent/Legal Guardian Date/Time of Signature

_____
Printed name of Parent/Legal Guardian (BLOCK CAPITALS)

_____
Printed Name of Subject (BLOCK CAPITALS)

The information about the study was described to the parent/legal guardian in language he/she understood.

_____ _____
Signature of Person Conducting the Informed Consent Discussion | Date/Time of Signature

_____
Printed Name of Person Conducting the Informed Consent Discussion (BLOCK CAPITALS)

Statement of the Witness (when applicable*)
The information in the consent form was accurately explained to and appeared to be understood by the child's parent/legal guardian. Informed consent was freely given.

_____ _____
Signature of Impartial Witness | Date/Time of Signature

_____
Printed name of Impartial Witness (BLOCK CAPITALS)

*Impartial Witness: If the subject's parent/legal guardian cannot read, the signature of an Impartial Witness is needed.

An impartial witness is:

- a person who is independent of the trial,
- who cannot be unfairly influenced by people involved with the trial,
- who attends the informed consent process, and
- who reads the informed consent form and any other written information supplied to the parent/legal guardian .