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AFLURIA QUADRIVALENT INFLUENZA VACCINE PREGNANCY REGISTRY
Informed Consent Form

Registry Coordination Center

1-800-901-5042 (toll-free telephone)
1-800-800-1052 (toll-free fax)
INC Research, LLC
1011 Ashes Drive
Wilmington, NC 28405

This informed consent is intended for patients who have reached the age of majority, emancipated minors, and parents/guardians of patients under the age of majority (minors). The Afluria Quadrivalent (QIV) Vaccine Pregnancy Registry, or Afluria Pregnancy Registry, is an observational research study called a 'Registry'. An observational research study is not an experiment. It is a study in which researchers collect and record health facts from routine health care. Any treatment of its participants is unchanged.

What Is This Study About?

Influenza vaccination at any time during pregnancy is part of the general recommendation of the US Advisory Committee on Immunization Practices to protect pregnant women against influenza and the associated risks of infection. Afluria QIV vaccine is one of several influenza vaccines licensed in the US and may be provided as part of routine care to protect humans against the seasonal influenza. Afluria QIV is produced by Seqirus Inc., a company with specific expertise in influenza vaccines.

This Registry will help us learn more about the safety of Afluria vaccine received at any time during pregnancy, by collecting data on pregnancy outcomes and other health events.

Since your or your minor's health care provider have indicated you or your minor received the Afluria QIV influenza vaccine during pregnancy, we are asking for you to be a part of this Registry which collects information on pregnant women such as yourself or your minor and your or your minor's baby or babies (in the case of a multiple pregnancy) following vaccination.

It is anticipated that approximately 550 pregnant women will participate in the Registry.

The collection of the information and other activities related to this Registry will be performed by Registry Coordinating Center staff at INC Research LLC, a research company who has been contracted by Seqirus to conduct this Registry.

What is protected health information (PHI)?

PHI is information that is gathered by a healthcare provider, health plan or researcher that identifies a patient or which includes facts that may tie a patient's identity to their health record. PHI includes:

- Information from a patient's existing or future medical records that is needed for the Registry, as described in this informed consent form; ***and/or***

- Information about a patient that is created during the conduct of the Registry, as described in this informed consent form.
- Examples of PHI which may be collected includes: demographic information, results of physical exams, histories and physicals, records of treatments, and information on the outcome of your or your minor's pregnancy and the health of your or your minor's baby/babies.

What do I have to do to participate?

To participate in this Registry your or your minor's routine health care will remain unchanged; no extra office visits, no extra tests, and no additional medications will need to be taken. No extra samples will be collected from you or your minor, or your or your minor's baby/babies for the purpose of this Registry.

If you agree to participate in the Registry, you are giving the Registry permission to request information about you or your minor, your or your minor's health and your or your minor's baby's/babies' health from the associated health care provider(s). You are also giving the Registry permission to contact:

- the health care provider who you or your minor are seeing during this pregnancy (obstetrician, midwife) to obtain information about you or your minor, the associated pregnancy and your or your minor's baby/babies.
- the health care provider who gave the vaccine to confirm which specific influenza vaccine was received and the date the vaccination was given.
- other health care provider(s) seeing you or your minor during the pregnancy or your or your minor's baby/babies health care provider(s) such as a pediatrician or nurse practitioner who may be able to provide any remaining information needed by the Registry. The Registry may contact these health care provider(s) directly or request your or your minor's obstetrician to collect the information needed for the Registry.

With your permission, the Registry will request information directly from your or your minor's health care provider(s). You may also be contacted by the Registry to provide information verbally over the phone.

For you to participate in this Registry, or for you to allow your minor to participate in this Registry, you must first provide your consent. You can give your consent verbally to the Registry Coordination Center by calling 1-800-901-5042 (toll-free number). Alternatively, you can provide your written consent by signing this form, and if applicable your minor signing the assent form, and mailing the form(s) to INC Research at 1011 Ashes Drive, Wilmington, NC 28405, or returning the form(s) to your or your minor's health care provider where this consent form was received.

What kind of information will be collected by the Registry?

The Registry will need information about you or your minor and the current pregnancy and medical/obstetrical history, maternal characteristics such as age, ethnicity, and race, and your or your minor's general health throughout the pregnancy and at the end of the pregnancy. We will ask you and/or your or your minor's health care provider(s) about the date you or your minor received the Afluria QIV influenza vaccine and any other drugs taken during this pregnancy. Your or your minor's health care provider(s) will be asked to provide information about the history of any previous pregnancies and their outcomes and information about any risk factors

related to your or your minor's pregnancy. At the end of the pregnancy we will ask about the pregnancy outcome and health of your or your minor's baby/babies, such as low birth weight or birth defects observed.

Information will begin to be collected at the start of your participation, or your consent for your minor to participate in the Registry (enrollment). Follow-up will occur at the end of the second trimester (around the 24th week of your or your minor's pregnancy) and at the end of pregnancy. You have the right to know what information is being collected and have the right to correct it as needed.

How will the Registry keep my information confidential?

Your or your minor's name, address, telephone number, and identifying information (such as medical record number or health plan number) may need to be used by the Registry to identify you or your minor for the purpose of collecting the required information from the associated health care provider(s) by the Registry Coordinating Center staff. You or your minor and your or your minor's baby's/babies' contact, identifying or medical information will be kept confidential within the limits of the law. The Registry will not reveal any information that identifies you or your minor, or your or your minor's baby/babies' by name outside the Registry and its contracted staff and Seqirus Inc.

Seqirus Inc., as producer of the vaccine, may have a duty or legal obligation to report certain safety information to the relevant authorities. This could include regulatory authorities such as the US Food and Drug Administration (FDA), or the Institutional Review Board (IRB) who is responsible for ethical oversight of this Registry. These governmental or other health authorities, the Institutional Review Board, staff of INC Research and of Seqirus' auditing group may inspect the Registry data files as permitted by law. The results of the Registry may also be reported to authorities who approve medicines, like the FDA. If information from this Registry is published in a medical journal or presented at scientific meetings, you, and if applicable your minor and your or your minor's baby/babies will not be identified by name or other personally identifying information. Health care providers who participated in the Registry will also receive information about the overall results of this study, but will only have access to identifiable data of their own registered patients. After the study is completed, the data collected in the study will be archived following the applicable regulations and guidance's, which is usually a period of 10 years.

How long does my permission last?

Your permission for your or your minor's health care provider(s) to provide information to the Registry remains valid until the Registry has ended.

Risks and Discomforts

The Registry uses a series of questionnaires to gather information and does not involve any medical procedures. For these reasons, the only risks or discomforts that are expected are related to the possible loss of confidentiality and/or the potential discomfort experienced when answering some of the questions.

If your or your minor's health care provider(s) cause injury or illness to you or your minor, or your or your minor's baby/babies outside the Registry, INC Research or Seqirus will not be held liable for any claim made in respect of such injury or illness.

Benefits
There are no direct benefits for your participation in this Registry, and there are no direct benefits to providing your consent for your minor's participation. There may be benefits to other vaccinated pregnant women in the future. The results of this Registry may increase medical knowledge about the safety of the Afluria QIV Influenza Vaccine during pregnancy.

Expenses
You or your minor will not have any additional expenses as a result of participation in this Registry.

Payment for Participation
You or your minor will not be paid for taking part in this Registry.

Alternatives
You or your minor may choose not to participate in this Registry.

Source of Funding
Funding for this research Registry is provided by Seqirus Inc.

What if I decide not to participate?
Your or your minor's participation in this Registry is voluntary. You may decide not to participate, or you may decide to not allow your minor to participate. Your or your minor's decision not to participate will not result in any penalty or loss of benefits to which you and your minor are entitled to. Your and your minor's and your and your minor's baby's/babies' medical care will not be affected by choosing not to participate in the Registry.

You may also withdraw from the Registry at any time, or you may withdraw your minor from the Registry at any time. If you choose to be a part of the Registry or you consent to allow your minor to be a part of the Registry, and decide later that you want to stop allowing information to be given to the Registry, you may let us know by sending a letter to the Registry at the address at the top of this informed consent form or you may contact us directly by phone at 1-800-901-5042 (toll-free number).

We will be allowed to use data collected before withdrawal of your consent or withdrawal of your consent on behalf of your minor. If you decide to withdraw from the Registry, your decision will not result in any penalty or loss of benefits to which you and your minor are entitled to.

Your and your minor's and your and your minor's baby's/babies' medical care will not be affected by choosing not to participate in the Registry.

Your and your minor's participation in this Registry may be stopped at any time at the discretion of your or your minor's doctor and the sponsor without your and your minor's consent for any reason.

New Information
You and your minor will be told about new information that might change your decision to be in this Registry, or your decision to allow your minor to participate in this Registry.

Questions
If at any time you have questions, concerns or complaints regarding this Registry, you may contact the Registry Coordination Center at 1-800-901-5042 (toll-free number) or you may let us know by sending a letter to the Registry at the address at the top of this informed consent form.

If you have questions, about your rights as a Registry participant or your minor's rights as a Registry participant, or if you have questions, concerns or complaints about the research study, you may contact:

Western Institutional Review Board® (WIRB®)
1019 39th Avenue SE Suite 120
Puyallup, WA 98374-2115
Telephone: 1-800-562-4789 or 360-252- 2498
E-mail: Help@wirb.com

Protocol Identification number for this Registry: V130_11OB

WIRB is a group of people who perform independent review of research. They help to protect the rights of people who are part of a research study.

WIRB may not be able to answer some Registry-specific questions; however, you may contact WIRB if the Registry Coordinating Center cannot be reached or if you wish to talk to someone other than the research staff.

Do not give your consent to participate or your consent for your minor to participate until you have had a chance to ask any questions you may still have and have received satisfactory answers to all of your questions.

If you agree to participate in this Registry, or you agree to allow your minor to participate in this Registry, you will receive a copy of this informed consent form.

Informed Consent
I have read the information in this consent form (or it has been read to me). The Registry representative from the Registry Coordinating Center or my health care provider, whose signature is given on this form, has informed me about the nature of the Afluria QIV Influenza Vaccine Pregnancy Registry. I have had enough opportunity to ask questions. All my questions about the Registry and my participation, or my minor's participation in it have been answered. I freely consent to participate in this Registry, and if applicable provide consent for my minor to participate in this Registry.

Parents/Guardians: You have the option of having your child, under the age of majority for your state of residence, join a research study. This is a parental permission form. It provides a summary of the information the research team will discuss with you. If you decide that your child can take part in this study, you would sign this form to confirm your decision. If you sign this form, you will receive a signed copy for your records.

By giving informed consent, I have not given up any of my legal rights.

☐ Verbal consent given by Participant to Registry Coordinating Center staff over the phone on: Date (dd/mm/yyyy)

OR

☐ Informed Consent process conducted by Participant's health care provider on: Date (dd/mm/yyyy)

Signature of ☐ Registry Coordinating Center staff or ☐ Health care provider — Date (dd/mm/yyyy)

Permission for a Patient* <u>who has reached</u> *the Age of Majority or Emancipated Minor to Participate in the Registry

Name of Participant — Date of Birth (dd/mm/yyyy)

Address of Participant

Phone number of consented participant:

Printed Name of Participant

Signature of Participant (optional) — Date (dd/mm/yyyy)

If written informed consent is provided, please sign and return **<u>one</u>** signed original to INC Research at 1011 Ashes Drive, Wilmington, NC 28405 in the pre-addressed, postage paid envelope provided. Please keep one copy of this form for your own reference.

Permission for a Participant Under the Age of Majority for Your State of Residence to Participate in the Registry

As parent or guardian, I authorize _____ (participant's name) to become a participant in the Registry described in this form.

Relationship to Participant: _____

For Participants Under the Age of Majority, Name of Parent/Guardian

For Participants Under the Age of Majority, Address of Parent/Guardian

For Participants Under the Age of Majority, Phone number of Parent/Guardian:

For Participants Under the Age of Majority, Printed Name of Parent/Guardian

For Participants Under the Age of Majority, Signature of Parent/Guardian (optional) Date (dd/mm/yyyy)

If written assent (by participant) and consent (by parent/guardian) are provided, please sign and return **both** signed originals to INC Research at 1011 Ashes Drive, Wilmington, NC 28405 in the pre-addressed, postage paid envelope provided. Please keep one copy of this form for your own reference.