Title: An Assessment of Immunogenicity of Respiratory Syncytial Virus (RSV) vaccines in residents of Long-Term Care Facilities (LTCF) and community-dwelling older adults receiving RSV vaccine as part of standard medical care

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INFORMED CONSENT FORM

Study Title: An Assessment of Immunogenicity of Respiratory Syncytial Virus (RSV) vaccines in residents of Long-Term Care Facilities (LTCF) and community-dwelling older adults receiving RSV vaccine as part of standard medical care

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KEY INFORMATION

You are invited to take part in a research study. This clinical trial is studying the newly licensed Respiratory Syncytial Virus (RSV) vaccines in adults over age 60 years living in long-term care facilities (nursing homes) by comparing the immune response to their vaccine to adults over age 60 years living in the community

Some key points about this study are listed below.

- Your participation in this study is completely voluntary.
- The main purpose of this study is to see if the RSV vaccines produce a good immune response in frail residents of nursing homes compared to those living in the community.
- You are being asked to take part in this study because you are planning to receive an RSV vaccine as part of your medical care.
- There are 2 scheduled visits over 1 month. (The first visit may be split into 2 visits).
- You will have your blood drawn twice during the study, one month apart.
- If you have been tested for viruses (Influenza, RSV, and COVID) in the one month between visit one and two, the study team will record those results.
- There are risks from participating.
  - The most common risk is pain or bruising from blood draw.

- See the “Risks of Participation” section in this consent form for more information. You should discuss these risks in detail with the research team.
- You will not benefit from being in this study.
- You will be compensated for your time and efforts in taking part in this study.

Please read this document carefully. Take your time to ask the study staff as many questions about the study as you want. The study doctor or study staff can explain words or information that you do not understand. Reading this form and talking to the study doctor or study staff may help you decide whether to take part or not. If you decide to take part in this study, you must sign and date at the end of this form.

BACKGROUND AND PURPOSE

Respiratory Syncytial Virus, commonly known as RSV, is a major cause of respiratory infection in all ages and can result in severe illness in both infants and older adults. Similar to flu, RSV infection is common in winter and can cause illnesses ranging from colds to bronchitis as well as severe pneumonia. Older age, and the presence of underlying medical conditions, particularly heart and lung disease, are risk factors for doing poorly with RSV infection. Outbreaks of infection are known to occur in Long Term Care Facilities (LTCFs).

Presently there is no specific treatment for RSV disease so prevention is important. Two adult RSV vaccines (made by GSK and Pfizer) are now licensed by the FDA and are available for adults 60 years or older. Although the trials demonstrated high efficacy there were very few residents of long-term care included in the clinical trials. This study will assess the antibody response (proteins the body makes to fight infection) to the licensed RSV vaccines in LTCF residents and compare their response to the antibody responses in adults over the age of 60 years living in the community. This information will help doctors and scientists decide if the vaccine will work as well in residents of LTCF as in healthy people living in the community.

A total of approximately 152 subjects (76 in LTCF and 76 in the community) will participate in this study.

If you are an employee or relative of an employee of this research center, you are under no obligation to participate in this study. You may withdraw from the study at any time and for any reason, and neither your decision to participate in the study nor any decision on your part to withdraw will have any effect on your or your family member’s performance appraisal or employment at this clinical research center. You may refuse to participate, or you may withdraw from the study at any time without penalty or anyone blaming you.

STUDY PROCEDURES

You will be in this study for 1 month. There will be 2 study visits during the study but possibly 3 visits if the first visit is split into 2 visits.

Screening/Vaccination: This visit can be separated into 2 visits or combined into a single visit. Screening might be done at a different time from vaccination if you have a temporary reason to delay vaccination such as illness or other recent vaccination.

Before we start any study-related activities, you will be asked to read, sign, and date this informed consent form.

- You will be asked about your race, ethnicity, and age.
- You will be asked about your medical history including vaccinations
- You will be given a brief target physical exam including your blood pressure, heart rate and temperature.
- You will be asked about medications you are currently taking

- We will draw your blood (approximately 2 teaspoons or 10 ml) to measure RSV antibodies.
- If you are visiting the clinic, the standard of care RSV vaccine will be available in the clinic for your convenience. As part of good clinical practice, you are asked to stay in the clinic for at least 15 minutes after vaccination.
- If you live in a nursing home, the staff at the facility will provide your vaccine in the next several days per their standard procedures.

Follow-up Visit at 1 month

You will be asked if there are any changes to your health or medications

- You will be asked if you have received any other vaccines.
- You will be asked if you had any respiratory illnesses and/or testing for viruses.
- If you live in LTCF, your medical record will be reviewed for any illnesses or changes in your health.
- We will draw your blood (approximately 2 teaspoons or 10ml) to measure RSV antibodies.

Additional Information

Should you become infected with RSV after enrollment, and before the standard of care RSV vaccination is given, we will proceed with visit 2 and collect your blood sample 4-6 weeks after infection in the absence of vaccination. We have added an additional serologic test to help distinguish natural infection compared to vaccination. Our hope should this situation occur, is to compare the immune response to natural infection to the response to vaccination. No additional procedures or blood samples will be collected compared to what was previously noted in the original application.

EXPECTATIONS

If you take part in this study, you will be expected to:

- Attend the study visits as planned
- Avoid getting RSV vaccination outside of this study

POTENTIAL RISKS AND BENEFITS

This study may be associated with risk due to sample collection or loss of privacy.

Sample collection: The collection of blood may be associated with bleeding, fainting, or infection in rare cases. Risks will be minimized by using experienced personnel for phlebotomy.

Loss of Confidentiality: Basic demographic and health information will be collected on subjects in this study and therefore breach of confidentiality is possible. Subject confidentiality will be maintained using study numbers on all data collection forms and keeping personal health information (PHI) separate. These documents are available to study personnel only and are kept under double-locked secure areas at the research center at the University. Only study numbers are written on the data collection forms.

Potential Benefits:

You will not benefit from being in this research study.

DISCUSSION OF FINDINGS

New information about the study: If we find out any new information that may affect your choice to take part in this study, we will contact you to explain what we have learned. This may be information we have learned while doing this study or information we have learned from other scientists doing similar research

in other places.

COSTS
There are no costs to you for taking part in this study. All study-related procedures, and study visits will be provided at no charge to you or your insurance company. You or your health insurance will have to pay for all costs of medical care that you get outside of this study.

COMPENSATION FOR PARTICIPATION
You will be compensated for your time and inconvenience for taking part in this study. You will be paid for the visits that you complete according to the following schedule:

- $100.00 for Visit 01 ($50 each for screening and vaccination days if separated)
- $50.00 for Visit 02

If you do not complete the study, for any reason, you will be compensated only for each study visit that you complete. You will be paid after completing each visit utilizing the Participant Payment system for taking part in this study. If you have any questions regarding your compensation for participation, please contact the study staff.

For this study, we use a subject payment system called Participant Payments. The system allows three ways to provide payment. You can choose a reloadable debit card; direct deposit; or mailed paper checks. The study team will help you create a "subject profile" in the system. In order to provide payment, you will need to enter your name and date of birth into your subject profile. Depending on which payment method you choose, you may also need to enter your email address and banking information. If you already have an account (because you are in another study that uses this system), your existing profile will be used to provide payment. See the 'Information Sheet for Participant Payments" for additional information.

Payment received for taking part in research is considered taxable income. If you receive payment for your taking part in studies at the University of Rochester of $600.00 or more in any one calendar year, the University is required to report this information to the Internal Revenue Service (IRS) in a 1099 (Miscellaneous Income) form. You will be sent a copy of this form and a copy will be sent to the IRS. You may be asked to submit a W-9 form, which includes your Social Security Number. If you are asked to complete a W-9 form and we find that you are not a US citizen or permanent resident, we may need to withhold 30% of your payment for taxes consistent with tax requirements.

CONFIDENTIALITY OF RECORDS
The University of Rochester makes every effort to keep the information collected from you private. In order to do so, once this consent form is signed you will be assigned a study code. During the study, the study doctor and study staff will collect your date of birth, gender, ethnicity, health data, and results of study tests. Your study samples and records will not include your name or personal identity but will identify you with the study code. This code can only be tracked back to you via a code key which is held by the responsible study doctor. Although procedures are in place to protect your privacy, absolute confidentiality cannot be guaranteed.

Sometimes, however, researchers need to permit review of information that may identify you with people who work for the University, regulators such as FDA monitors.

If you have never received a copy of the University of Rochester Medical Center (URMC) and Affiliates Notice of Privacy Practices, please ask the investigator for one.

What information may be disclosed to others?

- The investigator and study staff will get your personal and medical information.

- Research records
- Records about phone calls made as part of this research
- Records about your study visits
- Results of medical tests

Who may view information about you?

- The investigator and the study staff
- URMC and Affiliates

Your information may be disclosed to:

- The Department of Health and Human Services
- The University of Rochester Research Review Board
- Participant Payments
- The Office of Human Subject Protection (OHSP)
- The U.S. Food and Drug Administration (FDA) may also need to inspect study records at some point during the study or even after it has been completed. In the event that this should occur, every effort will be made to keep identifying information about you private.

Why will this information be disclosed to others?

- To do the research
- To study the results
- To see if the research was done correctly

If the results of this study are made public, information that identifies you will not be used.

What if I decide not to give permission to disclose my health information?
Then you will not be able to be in this research study.

May I review or copy my information?
Yes, but only after the research is over.

How long will this permission be valid?
This permission will last indefinitely

May I cancel my permission to use and disclose my information?
Yes. You may cancel your permission to use and disclose your health information at any time. You do this by sending written notice to the investigator. Upon receiving the written notice, the research team will no longer collect or disclose your health information and you will not be able to stay in this study. Information that has already been gathered may need to be used and disclosed to others for the validity of the study.

May I withdraw from the study?
Yes. If you withdraw your permission to be in the study, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and disclosed to others.

Is my health information protected after it has been given to others?
No. There is a risk that your information will be disclosed to others without your permission. Once your information is disclosed to the named entities or organizations listed above, it is possible that your medical information will be re-disclosed and will no longer be protected by U.S. federal privacy regulations.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

By signing and dating this consent form, you consent to the collection, access, use, and disclosure of your information as described above.

Please contact the study doctor at the telephone number listed on the first page of this consent document if you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects. If you have any questions about your rights as a research subject, contact:
For more information concerning this research or if you feel that taking part in the study has resulted in any research-related injury, emotional or physical discomfort, please contact:

Ann Falsey, MD at 585-275-7404, or after hours at 585-327-3644

Please contact the University of Rochester Research Subjects Review Board at 265 Crittenden Blvd., CU 420628, Rochester, NY 14642, Telephone (585) 276-0005 or (877) 449-4441 for the following reasons:

- You wish to talk to someone other than the research staff about your rights as a research subject;
- To voice concerns about the research;
- To provide input concerning the research process;
- In the event the study staff could not be reached.

VOLUNTARY PARTICIPATION
Taking part in this study is voluntary. You are free not to take part or to withdraw at any time, for whatever reason. No matter what decision you make, there will be no penalty or loss of benefit to which you are entitled. In the event that you do withdraw from this study, the information you have already provided will be kept in a confidential manner.

Use of E-mail in Research
You have the option to receive communications about this study via email and/or text messaging, by indicating your consent at the end of this form. Messages will be limited to appointment reminders. Email communications may be sent or received in an unencrypted (unprotected) manner. Therefore, there is a risk that the content of the communication, including your personal information, could be shared beyond you and the research team. Your consent below indicates that you understand this risk. The University of Rochester is not responsible for any interception of messages sent through email or texting. Email communications between you and the research team may be filed in your research record.

Place your initials in the YES OR NO box, based on your decision to take part.

Communication with the Study Team:

YES *(initial)*	**NO** *(initial)*	*I consent to the use of **email** in this study. If yes, enter email address:* _____

Subject Consent

I have read (or have had read to me) the contents of this consent form and have been encouraged to ask questions. I have received answers to my questions. I agree to participate in this study. I have received (or will receive) a signed copy of this form for my records and future reference.

_____

Subject Name (Printed by Subject)

_____ _____

Signature of Subject Date

_____

Legally Authorized Representative Name (Printed) Relationship to Subject

_____ _____

Legally Authorized Representative Signature Date

Person Obtaining Consent

I have read this form to the subject and/or the subject has read this form. I will provide the subject with a signed copy of this consent form. An explanation of the research was given and questions from the subject were solicited and answered to the subject's satisfaction. In my judgment, the subject has demonstrated comprehension of the information. I have given the subject adequate opportunity to read the consent before signing.

_____

Person Obtaining Consent (Print Name and Title)

_____ _____

Person Obtaining Consent (Signature) Date

Permission for Future Use of Blood Samples

During this study blood samples will be taken from you and will be stored at the University of Rochester Medical Center. The leftover samples may be useful for future research on respiratory tract infections and samples will be kept indefinitely. Your samples will be used only for research and will not be sold or used directly for the production of commercial products.

Sample Identification: Your samples will be labeled with a code so that your name cannot be readily identified. Any results from the research done on your leftover samples will not be put in your health/medical record and will be kept confidential. In the future, researchers studying your samples may need to know information limited to your age, gender, and race, and the researcher could be provided with this information collected as part of this study, but your name, social security number, or anything that might identify you personally would not be provided.

Risks: There are few risks to you from future use of your samples. Reports about research done with your samples will not be put in your health record but will be kept with the study records. Results from future research using your samples may be presented in publications and meetings, but your name will not be identified.

Freedom to Refuse: You can change your mind at any time about allowing your identifiable samples to be used for future research. If you do, contact a member of the study team and let them know. Then your samples will no longer be made available for research and will be destroyed. Whether or not you allow us to use your identifiable samples in future research, your decision will not have any effect on your participation in this study, or future participation in other studies.

Voluntary Consent:

(Please initial one)

1._____I do *not* agree to have my samples stored for possible future testing.

2._____I agree to allow my samples to be stored for future testing and research studies about respiratory tract infections and how the body responds to these infections with identifiers (codes on the samples) link your study data to the samples.

_____ _____

Participant Signature Date

_____ _____

Signature of Person Obtaining Consent Date