Approval Date: July 27, 2018
Approved Consent Version No.#2
PI Name: Kawsar Talaat
IRB No. 00008811

JOHNS HOPKINS BLOOMBERG SCHOOL OF PUBLIC HEALTH

INFORMED CONSENT DOCUMENT

Study Title:	**Phase I, Open Label, Inpatient Challenge Study of rRSV A/Maryland/001/11, a Human Respiratory Syncytial Virus Challenge Strain, Administered to Healthy Adult Volunteers.**
Sponsor:	**National Institute of Allergy and Infectious Diseases (NIAID)**
Principal Investigator:	**Kawsar Talaat, M.D.**
IRB Protocol No.:	**CIR 320**
PI Version Date:	**Version 2.0 July 26, 2018**

What You Should Know About This Research Project

- You are being asked to join a research study.
- This informed consent document explains the research study and your part in the study.
- Please read it carefully and take as much time as you need.
- This consent form may contain words that you do not understand. Please ask the study doctor or the study staff to explain any words or information that you do not understand.
- Do not sign this document unless all your questions about the research study have been answered to your satisfaction.
- You are a volunteer. You can choose not to participate, and if you choose to participate, you may quit at any time. There will be no penalty if you decide to quit the study.
- During the study, we will tell you if we learn any new information that might cause you to change your mind about participating in the study.
- 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.
- If you would like to review the information for this study, or a summary of results, ask the study doctor for the ClinicalTrials.gov study registration number.

Purpose of the Research Project

The purpose of this research project is to learn about the safety and immune (germ-fighting) response in healthy adults to the virus (germ) called Respiratory Syncytial Virus (rRSV A/Maryland/001/11). This type of study is called 'a challenge study'. An experimental challenge is one that has not been approved for marketing or sale by the U.S. Food and Drug Administration (FDA). The FDA is allowing the use of experimental RSV challenge in this study.

Experimental human studies have been used for many years to look at a number of potential vaccines and treatments for many illnesses. Controlled human infection studies can provide insights into how the

virus affects the body and the immune (germ fighting) response to the illness. There have been many human RSV challenge studies involving more than 300 people without reported serious adverse events.

Background Information
RSV is the most common cause of infant respiratory tract infection in the world. It is also a major cause of illness and death in immune compromised people and the elderly. Currently there are no vaccines or antivirals available to prevent or treat this illness.

The Laboratory of Infectious Diseases (LID) at the National Institute of Allergy and Infectious Diseases (NIAID), within the National Institutes of Health (NIH), has a long history of vaccine development in partnership with the Center for Immunization Research (CIR) at Johns Hopkins Bloomberg School of Public Health (JHSPH).

Rationale
Understanding how the RSV virus works may lead to the development of a vaccine or antiviral in the future, therefore, we would be able to prevent or treat this illness.

Information about the experimental Challenge product:
The virus being used in this challenge study was recovered in Maryland from an adult who developed a respiratory tract infection. It was produced as a challenge strain identical to the one from the original person. This RSV challenge strain has never been administered to humans. Other RSV challenge strains have been given to more than 300 people in other RSV challenge studies. If you join the study, you will be given the RSV germ by a nose spray.

Why You Are Being Asked to Participate
Twenty healthy, adult volunteers are needed for this study to learn more about RSV disease as well as the investigational rRSV A/Maryland/001/11 challenge strain. We will watch very closely for symptoms caused by RSV. Each volunteer will receive 1 dose of RSV challenge. You will spend at least 10 days in the inpatient unit, including the day of admission and discharge. The experimental challenge will happen the day after you are admitted to the unit. You will be monitored carefully for symptoms of RSV and any health concerns. The information learned could be used to test the efficacy of a vaccine or antiviral in the future.

Basic Eligibility Requirements
You are being asked to participate in this study because you joined our screening study where you were found to meet the basic eligibility requirements. We will verify that you are still eligible.

Now we are asking you to participate in this screening and consent visit for the study: **Phase I, Open Label, Inpatient Challenge Study of rRSV A/Maryland/001/11, a Human Respiratory Syncytial Virus Challenge Strain, Administered to Healthy Adult Volunteers.** Today, we will provide you with a complete description of the study and are asking you to:

- Read this consent for participation in the challenge trial carefully and thoroughly.
- Show that you understand this research by completing a comprehension assessment, receiving a score of 70% or better, and understanding the questions answered incorrectly.
- Sign this document indicating your consent to participate in this study.
- Complete a physical exam.

- Vital signs (heart rate, blood pressure, temperature, respiratory rate, and pulse oximetry) may be measured.
- If not already done during a prior screening visit, height, weight and BMI will be obtained.
- If not already done during a prior screening visit, provide blood samples for laboratory tests, including:
    - Complete blood count with differential
    - Blood chemistries (including tests of your liver and/or kidney function)
    - Serum pregnancy test (females only)
    - HIV test: State law requires that the results of positive tests for HIV be reported to a local health agency. If any screening tests are abnormal, the study staff will tell you. You will be referred to your primary medical provider for follow-up care. A separate HIV testing education form explains how positive results are reported to the local health department. Counseling will also be made available to you to discuss a positive HIV test.
    - Hepatitis B and hepatitis C tests: State law requires that the results of positive tests for hepatitis be reported to a local health agency.
    - Blood for RSV titer and other research samples.
- If not already done during a prior screening visit, provide a urine sample for drug testing. The results of the urine drug test are health protected information and will be held in confidence by study personnel.
- Accept pregnancy prevention counseling if you are a female.
- Read and agree to comply with the **Inpatient Unit Rules**, **Alternate Agreement**, and **Handwashing Best Practice**.
- You will be evaluated to see if you are eligible for the study (review some of the inclusion and exclusion criteria.

These eligibility criteria include:

- You are 18–50 years of age.
- If you are female, you are not pregnant or breast-feeding, and you are not at risk of becoming pregnant during the active study period for reasons such as one or more of the followings:
    - Menopause, you have had surgery to remove your uterus and/or ovaries or tie or permanently block your tubes (tubal ligation or Essure), or you do not have sex with men,
      or
    - You are consistently using a pregnancy prevention method per label instructions to achieve maximum protection against pregnancy initiated at least one month prior to enrollment and throughout the duration of the study. Acceptable methods of pregnancy prevention are: condoms with spermicide, diaphragm with spermicide, Intrauterine device, birth control pills, birth control patch, birth control implant, or birth control shot (Depo-Provera).

***The active study portion is 56 days from the dose of the investigational challenge.**

Key Study Procedures

We plan to enroll one group of 20 volunteers. You are enrolled when you receive the investigational product.

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The study will be divided into 3 parts:

1. Screening: You will have 1-2 screening visits to give you information about the study and see if you are healthy enough to join. More visits may be needed if any of your screening tests are abnormal.
2. Inpatient Challenge Phase: If you are eligible, you may be admitted to the CIR (Center for Immunization Research) Inpatient Unit at Johns Hopkins Bayview Medical Center. The first day we will assess you for continued eligibility. The next day (Day 0), you will receive the RSV challenge in your nose from a sprayer. You will spend about 10 days in the unit. We will monitor you, and you may develop RSV symptoms (cold like symptoms). You will be discharged after you have had 2 consecutive nasal washes with low levels of the RSV virus (below a certain level) on Day 6 or later. Discharge usually happens by Day 8 (10 days after admission to the unit). However, if you are still shedding the RSV germ, we will ask you to remain on the unit.
3. Outpatient follow-up: After discharge from the inpatient unit, you will return to the CIR for 3 outpatient follow up visits, about 10, 28 and 56 days after receiving the investigational product. This visit should last 1-2 hours. There will be a final follow-up contact about 6 months after you received the RSV germ. We will ask if there have been any significant health events, new chronic conditions or hospitalizations.

Inpatient Challenge Phase: (Day -1 to Day 8 (+))

On admission day, about 25 volunteers will be invited to come to the CIR inpatient unit. About 23 will be admitted. You will be admitted 1 day prior to challenge.

In order to limit the potential spread of RSV to other people, your activities will be restricted to the unit during the admission and you will be asked to use proper handwashing. The inpatient unit is a smoke-free, vapor-free, dorm-like setting where you will live, sleep, and eat with other volunteers. It is well-equipped and comfortable. Visitors are not allowed. It is likely that you will be woken up about 5:45 am most mornings so that we can collect required specimens.

If you accept the challenge and are enrolled in the study, you must stay on the unit 24 hours/day until the study doctor says it is safe for you to be discharged.

On Day 0, 20 subjects will be selected to enroll in the study and receive challenge. Volunteers not selected to be enrolled (challenged) will be discharged and there will be no further follow-up.

Day -1: Admission to the Inpatient Unit:

- You will be admitted to the unit.
- Your personal property will be checked and inventoried.
- We will review your health status, medications and inclusion and exclusion criteria to confirm you are still potentially eligible.
- Vital Signs (blood pressure, temperature, heart rate, respiratory rate and pulse oximetry) at least twice daily.
- You will have a complete physical exam (PE) will be done on admission.
- You will provide blood (up to 6 tablespoons).
- You will have a nasal wash and nasal strip tests done.

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- If you are female, we will draw blood for a pregnancy test.
- Vital sign information, blood collection, urine tests, and nasal washes may be repeated as needed to confirm eligibility.
- You will blow into a machine (spirometer) to check your breathing.

Day 0: Enrollment, Challenge Day:

- Vital Signs at least 3 times this day.
- Focused PE prior to challenge.
- Study criteria will be reviewed to confirm you are still eligible.
- Females will have a urine pregnancy test.
- You will have a nasal wash and the nasal strip test done.
- 20 eligible and willing subjects will receive challenge with rRSV A/Maryland/001/11 (0.25 ml of investigational product will be administered to each nostril (total 0.5 mL).
- You will be observed for at least 30 minutes after administration to evaluate for immediate adverse reactions, followed by an additional set of vital signs.
- If not done on day -1, you will blow into a machine (spirometer) to check your breathing.

Day 1 – 7: Inpatient Monitoring:

- Focused PE at least daily.
- You will be asked about symptoms you would be expected to have with an RSV infection.
- Review of adverse events/clinical symptoms.
- Vital Signs at least twice daily.
- You will be asked to provide blood (up to 6 tablespoons) and nasal strip on Days 4 and 7.
- You will be asked to provide a nasal wash daily.
- You will be asked to blow into the spirometer at least once.

Day 8: Planned Discharge from Inpatient Unit:

- You will be discharged from the unit on Day 8 if your nasal wash sample has been below the target level for challenge virus for 2 consecutive days.
- Focused PE prior to discharge.
- Review of adverse events or any symptoms.
- If you are eligible for discharge, at least one set of vital signs measured and you will blow into the spirometer before you go.
- If you do not meet criteria for discharge, you will need to stay on the unit to be assessed as above and to reduce the risk of spreading the challenge virus to others once you leave the unit.
- If you are not being discharged, you will have a nasal wash daily and vital signs taken twice a day until discharge criteria are met.
- Research staff may obtain a blood sample (up to 6 tablespoons).

Day 9 – until Discharge (only for subjects not meeting criteria for discharge earlier)

- You will be discharged once shedding is negative or below the target level for challenge virus.
- Nasal wash for RSV virus.
- Focused PE prior to discharge.
- Review of adverse events.
- If you are eligible for discharge, at least one set of vital signs measured before you go.

- You will be asked to provide nasal wash specimen.
- You may be asked to provide blood (up to 6 tablespoons).
- For subjects who do not meet criteria for discharge, they will remain on the unit.

Outpatient follow-up
If you are discharged before Day 10, we will ask you to return for a visit on Day 10 after challenge. If you are still inpatient, these procedures will occur while you are on the unit:

Day 10:
- You will return to the CIR for a brief outpatient visit.
- Research staff will ask you about your health and any medications since discharge from the unit.
- If you have any symptoms you will have a physical exam.
- Your vital signs (blood pressure, heart rate, respiratory rate and temperature) will be obtained.
- You will be asked to provide blood (up to 6 tablespoons).
- You will be asked to provide nasal wash and nasal strip.

Day 28 (± 3 days) and Day 56 (+/-7days) after challenge
- You will return to the CIR for a brief outpatient visit.
- Research staff will ask you questions about your health and any medications since discharge from the unit.
- If you have any symptoms, you will have a physical exam.
- Your vital signs (blood pressure, heart rate, respiratory rate and temperature) will be obtained.
- You will be asked to provide blood (up to 6 tablespoons).
- You will be asked to provide nasal wash and nasal strip.
- Urine pregnancy test on Day 28 only (females).

Day 180: 6 – month (+/- 21 days) Follow- up contact:
- We will contact you by phone, text, e-mail or mail about 6 months after you received the challenge to complete the follow-up call. We will ask you if you have experienced any serious, new chronic illnesses, hospitalizations, or other new serious health events.

Volunteer's Responsibilities
- For your safety and for research purposes, it is very important that you complete all of your outpatient follow-up visits on time.
- Follow all study requirements.
- Provide nasal, blood and urine samples.
- Tell the study team of any medical events and/or all medications you are taking.
- Remain in contact with study investigators through the Day 180 follow up contact.
- Do not participate in other investigational studies through Day 56 of this study.
- While in the inpatient unit, you are agreeing to:
    - Stay on the unit until you are eligible for discharge, not have visitors, and to follow the rules. The rules are to help keep everyone comfortable and safe. You will receive a copy of these rules to review and to sign in agreement. If you break these rules, you may forfeit some or all of your bonus and/or be asked to leave the unit.

Risks/Discomforts
In this study, there are risks related to the investigational challenge and risks related to study procedures.

Risks Related to the Investigational RSV Challenge
This is an experimental challenge product. It has never been administered to humans. We can tell you what we think the risks will be based on research in animals and human trials of other experimental RSV challenge strains.

The expected side effects from this challenge would be illness similar to RSV illness (cold like illness in healthy adults). Symptoms include:

- Runny nose
- Sneezing
- Cough
- Headache
- Sore throat
- Shortness of breath
- Nasal congestion
- Fever (T $\geq$ 100.4°F)
- Malaise (feeling poorly)
- Upper respiratory infection (cold)
- Ear infection

Less common, but potential side effects include:

- Lower respiratory infection (bronchitis or pneumonia)
- Wheezing
- Low oxygen levels or severe problems breathing

Side effects are expected to be mild or moderate. It is possible that the rRSV A/Maryland/001/11 challenge strain could cause a more serious illness, although this has not been seen in other RSV human challenge studies. If you become ill, we will give you medication and supportive care to relieve your symptoms and reduce discomfort. We will continue to monitor your nasal washes and lab results until we are sure that you are not experiencing serious side effects and cannot give the virus to others. You will not be discharged until the Principal Investigator (PI) or designee determines that it is safe for you to leave the unit. There may be other side effects that we do not know.

Allergic reactions such as hives, asthma, and anaphylaxis are a possibility whenever you are exposed to something new. Anaphylaxis is a rapid, severe allergic reaction that could result in death. The study medical staff will watch you carefully for 30 minutes after you are challenged. We will treat you immediately for any signs of an allergic reaction.

Transmission of challenge virus – To decrease the risk of giving this germ to others after discharge, you will not be discharged until you have 2 consecutive nasal wash results that are below the target level for challenge virus. If you leave the unit prior, there is a chance you could give this germ to someone, this is why it is very important that you agree to remain on the unit until you meet discharge criteria. You should wash your hands frequently and stay away from very young children, old people,

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and immune-compromised people like those with HIV or history of organ transplant until your nasal wash is below the target level for challenge virus. This will minimize the risk of transmitting the RSV virus.

We will let you know if there are any unanticipated side effects and if new information becomes available that may impact your decision to continue in the study.

Risks Associated with Study Procedures

- **Blood drawing** – can cause pain, bruising, bleeding, and, rarely, infection at the puncture site. Sometimes, drawing blood can cause people to feel lightheaded or to faint.
- **Nasal wash collection** – can cause mild discomfort and rarely, a nosebleed. This is like getting salt water in your nose when swimming in the ocean.
- **SAM (nasal) strip collection**– may cause mild discomfort and very rarely, a nosebleed.
- **Isolation** – you may feel bored or anxious about being separated from loved ones while you are in the unit. You may need to stay in the unit longer than you anticipated. The unit will be staffed around the clock. There will be activities you can choose to participate in. There are big screen TVs, games, a kitchen, and a dining area.
- **Transmission of challenge virus** - If you are still shedding the RSV virus on discharge, there is a small chance of transmitting the virus to others.

Pregnancy and Breastfeeding

The effects of the challenge on the unborn fetus and breastfeeding infant are not known. Women who are pregnant or breastfeeding will not be eligible to participate in the study. All women who can become pregnant must agree to consistent use of an effective birth control method. Ask the study doctor for information about effective birth control if you are not satisfied with your current method. We may be able to refer you to a practitioner who can help you choose a method that is right for you. A pregnancy test will be done during screening, admission, prior to challenge, and on Day 28. This test must be negative before the staff will give you the challenge.

Please tell the study staff right away if you become pregnant. We will ask you to come in for your regularly scheduled study visits or ask you to agree to let us keep checking on you until the end of your pregnancy. You will be asked to sign a medical release form so that we can learn about your pregnancy and your baby's health at birth.

Smokers

History of smoking and/or vaping is exclusionary for this study and is not allowed on the inpatient unit.

Nasal Wash procedure:

A nasal wash is done by dripping about 2 teaspoons of sterile solution into one nostril at a time, then allowing the solution to dribble out of your nose and into a sterile cup. The solution does not burn and it will not hurt you if you swallow. This procedure seems odd at first, but you will be guided through it step by step.

Nasal strip (SAM Strip):

The nasal strip is placed into your nostril and the nostril is pinched closed for about 30 seconds to absorb fluid, then removed. It may feel a little odd, but is not painful.

Blood Draws:
Blood samples to measure your immune and antibody response (the body's infection fighting ability), will be taken during the study. The most blood to be taken on any day is about 6 tablespoons (90 ml). The total blood to be drawn over the course of the study is about 1 cup. There are about 7 scheduled blood draws during the whole study.

Do Not Participate in other Studies during This Study
Because this study involves experimental product, the challenge, we do not know what will happen if you take another investigational product at the same time. You could significantly increase your risk of illness and injury if you take more than one investigational product at a time.

Medications
Tell us of ALL medications you are taking. We are looking at your immune (germ-fighting) response to the challenge. It is important for you to let the study doctor know all medications including over the counter or prescription medications that you are taking. Other vaccines, medications, or treatments might interfere with the germ-fighting ability you develop in response to the study challenge.

If You Become Ill
We ask that you notify the study staff if you become ill at any time while you are in the study, even if you do not think it is related to the study product. A study doctor will be available by phone or pager at all times during the study. A study nurse is also available by phone at all times if you have any questions. The study doctor, Dr. Kawsar Talaat, can be reached at 410-502-9627 or 410-336-9164 (24 hours), and the study nurse, Barbara DeNearing RN, BSN can be reached at 410-550-2725 (24 hours).

New Findings
We will let you know if we learn anything new about the investigational challenge that suggests new or increased risks of study participation or leads to changes in our research plan. You may be asked to repeat the informed consent process to ensure you are aware of any changes affecting your participation in the study and confirm that you agree to them.

You should ask the study doctor listed below any questions you may have about this research study. You may ask questions in the future if you do not understand something that is being done.

Benefits

There is no direct benefit to you participating in this research study. If you are included in the study, you will get physical assessments and laboratory tests as part of the study procedures. These results will be available for you if you would like them. If any health problems are identified during the course of the study, you will be referred for care. This does not take the place of regular visits to your health care provider

Participating in research may benefit society by helping researchers and doctors learn about RSV.

Compensation
If you are enrolled in the study and complete all study visits and procedures on time and follow all the rules, you will receive the following compensation:

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- $80 total for all screening visits for the study if you are enrolled in the study or fulfill the alternate requirements
- If enrolled: you will be paid $1,900 for the inpatient phase (as long as all study requirements are met)
- $80 for each outpatient visit, Day 10 (only if not inpatient), Day 28, and 56 (total $240)
- $60 for Day 180 follow up contact
- $300 bonus upon successful completion of the inpatient phase and outpatient visits
- Total compensation: $2,580

You will not be paid for missed visits and may forfeit some or all of your bonus as a result of missed or late visits or non-compliance. You will not be compensated for days you do not complete during the inpatient phase if you leave the unit early or are asked to leave the unit early due to non-compliance.

If you present to the unit as an alternate and not admitted, you will receive $80 for completion of the screening visits and $190 for coming to the unit that day (total $270). If you are admitted to the unit, not selected for challenge, and discharged prior to challenge as an alternate you will receive $80 for screening and $190 for each day on the unit (total $460). The Alternate agreement form will explain requirements in more detail.

If it takes extra time on the unit to satisfy discharge criteria, you will be paid $190 per additional day. If you are required to complete additional outpatient visits, you will be paid $80 per visit.

To comply with federal law, we will collect your social security number and will report payments as income to the Internal Revenue Service (IRS).

If you choose to withdraw or the study is stopped before the study is completed, you will receive payment for the portion of the study that has been completed.

Protecting Data Confidentiality
We will take the following steps to protect the safety of your research data and the information you share with us while you are a study volunteer:

- Your study data and biological samples will be identified by a unique study ID, not your name.
- Your study data will be stored in locked cabinets and/or password-protected computer files.
- Your name, birth date, and social security number are not given to anyone unless required by law.

Information describing the study will be posted on a clinical trials registration website. This website can be accessed at https://clinicaltrials.gov/. Information from this study will be given to the sponsor. The sponsor is the organization who is financing and overseeing the study. The sponsor of this study is the National Institutes of Health (NIH), National Institute of Allergy and Infectious Diseases (NIAID), Office of Clinical Research Policy and Regulatory Operations (OCRPRO). “Sponsor” includes any persons or companies that are contracted by the sponsor to have access to the research information. Information about side effects will be given to the US Food and Drug Administration (FDA). Medical records which identify you, including photographs, and the consent form signed by you will be looked at and or copied for research or regulatory purposes by the sponsor, and may be looked at and/or copied for research or

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regulatory purposes and groups who make sure that the study is conducted safely, ethically, and according to federal regulations. These groups may include:

- Department of Health and Human Services (DHHS) agencies
- Governmental agencies to who certain diseases must be reported
- Governmental agencies in other countries
- Johns Hopkins University
- The Johns Hopkins University Bloomberg School of Public Health
- Audit and compliance officers and legal counsel
- The Office for Human Research Protections (the government agency that makes sure that we are conducting the research as planned)
- The U.S. Food and Drug Administration (FDA) and similar regulatory agencies
- The medical monitor is a physician who is not involved in running the study, but who has agreed to help protect your safety. This physician will review the safety data from this study regularly and will give advice to the investigator if he or she is concerned about any of the safety information.
- The Maryland State Health Department
- There will be people working on the study who need to see your research information. These people may include the researchers, study and lab personnel, and other research study staff.

These people are required to keep your identity private. Maryland state law requires us to report some diseases and information about child abuse. If reported, this information may not remain confidential. Otherwise, the information that identifies you will not be given out to people not working on the study, unless you give us permission.

Absolute confidentiality cannot be guaranteed because of the need to give information to these parties. The results of this research study may be presented at meetings or in publications. Your identity will not be disclosed in those presentations.

Protecting Volunteer Privacy during Data Collection
All volunteer assessments and study procedures will take place in private areas.

Alternatives to Procedures or Treatments
This is not a treatment study. The study product is not a cure for any pre-existing health conditions. You are a healthy adult. You may choose not to participate in this study.

Biological Specimens
The biological specimens you give us during this study are important to science. Any unused blood or nasal wash specimens will be stored for future use. Agreeing to sample storage is a requirement of study participation. You should not join the study if you do not want your samples to be stored. You will not own your biological samples after you give them to the study. You will not receive any financial benefit from any product or idea created by using the data or biological samples collected from you.

Your blood and nasal samples may be used for future research to learn more about RSV. Samples may be stored at the CIR, LID, NIAID, and/or NIH for an indefinite time period. These samples will be used only for research. Your blood may be used to test markers on your white blood cells and genes and to look for proteins in the blood that may be important for your body to fight RSV infection.

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Your samples will be coded so that they cannot be linked to you. Reports about research done with your samples will not be put in your health record. There will be no direct benefit to you from any future research use of your samples, but we may learn more about how to prevent and treat illnesses caused by RSV. Results from future research using your samples may be presented in publications and meetings, but you will not be identified as a study volunteer.

There are risks associated with a loss of confidentiality of your health information and genetic testing results. Information about genetic test results may affect your employment, insurance, or family relationships. The sponsor cannot be certain that your genetic test results could never be linked to you.

A Federal law called the Genetic Information Nondiscrimination Act (GINA) provides some protection for your genetic information. This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information collected in this research.
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information collected in this research when making a decision about your employment.

However, this Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

If you do not want your unused samples used for future research, you should not join this study.

You can change your mind at any time about allowing your samples to be used for future research. If you do change your mind, call or write the study doctor or study nurse and let them know. Then your samples will no longer be made available for research. Your samples will be destroyed.

Cost of Participating in the Study
There are no expected costs to you for being in this study. Ask your study doctor to discuss the costs of treating possible side effects. Otherwise, you might have unexpected expenses from being in this study.

What Happens if You Leave the Study Early?
Your participation in this study is voluntary. You may decide not to participate and you may leave the study at any time. If you decide to withdraw from the study soon after you are challenged, the study doctor may ask you to return to the clinic for evaluation for safety reasons. We may ask you for nasal specimens so we can see if you are shedding the RSV virus.

Your decision not to participate or to withdraw from the study will not result in any penalty or loss of benefits to which you are entitled. Your decision not to participate in the study will not put at risk any present or future employment at Johns Hopkins University, nor impact your medical care at any Johns Hopkins medical facility.

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If you decide to leave the study, your unused samples will be further used for the research explained above, unless you provide a written request for your samples to be destroyed. Data collected during the study period prior to your decision to leave will be used.

You may be withdrawn from the study at any time by the study doctor or the sponsor without your consent if:

- The study sponsor decides to stop or cancel the study for any reason
- The study staff or the study sponsor decides to discontinue your participation for any reason
- The study staff or the study doctor feels that staying in the study is harmful to your health
- You do not follow instructions from the study staff or do not keep appointments
- The FDA or JHSPH Office for Research Subjects feel the study should be stopped
- You do not consent to continue in the study after being told of changes in the research that may affect you

Certificate of Confidentiality
Your study information is protected by a Certificate of Confidentiality. This certificate allows us, in some cases, to refuse to give out your information even if requested using legal means.

It does not protect information that we have to report by law, such as child abuse or some infectious diseases. The certificate does not prevent us from disclosing your information if we learn of possible harm to yourself or others, or if you need medical help.

Disclosures that you consent to in this document are not protected. This includes putting research data in the medical record or sharing research data for this study of future research. Disclosures that you make yourself are also not protected.

Payment of Treatment Costs for Injury or Illness from Study Participation
A study doctor will be available at all times while you are in the study to check on you and treat you for any short-term medical care needs resulting from your participation in this research study. This short-term medical care will be paid through our contract with NIH. Short-term medical care will be given at a facility determined by Johns Hopkins Hospital and NIH.

In general, the Johns Hopkins University (JHU), Johns Hopkins Hospital, NIH, or the federal government will not routinely provide long-term medical care or financial payment for research-related injuries. At your request, your insurance company can be billed for payment of any such treatment or hospitalization. Check with your insurance company before you start this study to find out what your insurance company will pay for. JHU, JHH, JHBMC, NIH and the federal government do not have a program to pay you if you are injured or have other bad results from being in the study. However, you do have the right to seek legal counsel if you believe that your injury justifies such action.

Who Do I Call if I Have Questions or Problems?
If you have any questions about your participation in this study; have any questions, concerns, or complaints about the research; or, at any time, feel you have experienced a research-related injury or a reaction to the study vaccine, contact:

STUDY-RELATED Kawsar Talaat, MD (Principal Investigator)

	Approval Date: July 27, 2018 Approved Consent Version No.#2 PI Name: Kawsar Talaat IRB No. 00008811

PHONE NUMBER(S): 410-502-9627
410-336-9164 (24 hours)
Or
Barbara DeNearing (study coordinator)
410-935-6938 (24 hours).

Call or contact the JHSPH IRB Office if you have questions about your rights as a study volunteer. Contact the IRB if you feel you have not been treated fairly or if you have other concerns. The IRB contact information is:

Address:	Johns Hopkins Bloomberg School of Public Health 615 N. Wolfe Street, Suite E1100 Baltimore, MD 21205
Telephone:	410-955-3193
Toll Free:	1-888-262-3242
E-mail:	JHSPH.irboffice@jhu.edu

The IRB reviewed this study and gave a favorable opinion. The IRB reviewed this study to help ensure that your rights and welfare are protected and that this study is carried out in an ethical manner.

Your Signature on This Form Means:

- You have been informed about this study's purpose, procedures, and possible benefits and risks.
- You have been given the chance to ask questions before you sign.
- You have voluntarily agreed to participate in this study.
- You are aware that nothing contained in this informed consent form waives any of your legal rights as a research subject, nor does it release the study doctor, the sponsor or its agents from any liability for negligence.

Print Name of Adult Participant	Signature of Adult Participant	Date	Time

Print Name of Person Obtaining Consent	Signature of Person Obtaining Consent	Date	Time

Give one copy to the volunteer and keep one copy in study records.