Participant Information and Consent Form

Study Title: Assessment of QBKPN Site Specific Immunomodulator (SSI) Efficacy in Improving Innate Immune Function and Reducing All-Cause Respiratory Tract Infection Morbidity in Adults 65 Years of Age or Older Residing in the Community, in Independent-Living, Assisted-Living and Long-term Care Facilities (RESILIENCE Study)

Short Title: RESILIENCE Study

Protocol Number: QBKPN-IS-01

Study-wide Principal Investigator:
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Sponsor(s)/Funder:
Qu Biologics, Inc.
4475 Wayburne Drive, Suite 305
Burnaby, British Columbia, V5G 4X4
CANADA and

The National Research Council of Canada Industrial Research Assistance Program

Emergency/Non-emergency Contact Number (24 hours/7 days a week): Study nurse cell number: 236-514-5955

Invitation

You are being invited to take part in this research study because you are living in the community, in an independent-living, assisted-living or long-term care facility and are in an age group (65 years or older) that puts you at high risk for respiratory and other infections, as well as an increased risk of cancer and chronic inflammatory diseases due to the aging process.

The study that will be described to you in this consent form is about a new investigational treatment called QBKPN SSI. Please take time to read the following information carefully and discuss it with your family, friends, and/or doctor before you decide. If you wish to participate in this study, you will be asked to sign this form. You should not sign this form until you understand all the information presented in the following pages and until all your questions about the research have been answered to your satisfaction.

Your participation is voluntary

Your participation is voluntary. You have the right to refuse to participate in this study. If you decide to participate, you may still choose to withdraw from the study at any time without any negative consequences to the medical care, education, or other services to which you are entitled or are presently receiving.

Being in a study is not the same as getting regular medical care and does not replace your regular medical care. When you are involved in a study, you are called a “study participant” which is a term you will see in this form.

Who is conducting this study?

This study is being conducted and sponsored by Qu Biologics, Inc., with funding received from the National Research Council of Canada Industrial Research Assistance Program. Qu Biologics, Inc. is the manufacturer of the investigational new treatment, called QBKPN SSI. Qu Biologics, Inc. is paying the study facilities and study doctors to conduct this study. Qu Biologics, Inc. may benefit from commercialization of the research findings in the future. However, you will not receive any financial compensation.

The Principal Investigator, Dr. Theodore Steiner, from the University of British Columbia, is the Sponsor’s Chief Medical Officer – Infectious Diseases and has received financial compensation from the Sponsor, Qu Biologics, Inc., for the work required in doing this clinical research and for providing advice on the design of the study. Other employees of Qu Biologics may be involved in administrative aspects of running the study as well. Financial compensation to site researchers and staff for conducting the research is associated with obligations defined in a signed contractual agreement between the researchers, institution and the Sponsor. Researchers must serve the interests of the participant and also abide by their contractual obligations. For some, the payment of financial compensation to the researchers can raise the possibility of a conflict of interest. You are entitled to request any details concerning this compensation from the Principal Investigator.

Background

As people age, their immune systems may not work as well. This decline in immune function increases the chances of getting respiratory and other infections, cancer, chronic inflammatory diseases, and reduced response to vaccines. There is a need to find treatments which may restore or improve immune function for older adults.

The investigational treatment being studied is called QBKPN SSI. It is targeted for the prevention of respiratory infections. QBKPN SSI contains components of one type of a killed bacterium (germ), called *K. variicola*. QBKPN SSI does not contain live bacteria and therefore cannot cause infection. It is believed that QBKPN SSI can work with your immune system to help protect against respiratory infections, cancer, and chronic inflammatory diseases.

This study is trying to further look at the safety of QBKPN SSI, and to find out what effect the drug QBKPN SSI has on your immune system, including how well it can protect you from respiratory and other infections; whether or not it improves your body’s response to COVID-19 vaccines (if you have received these) and what effect it has on maintaining or improving your quality of life, activity level and health status.

Health Canada has not approved the sale or use of QBKPN SSI to prevent respiratory or other infections, cancer, or chronic inflammatory diseases or to improve response to COVID-19 vaccines, to maintain or improve your quality of life, activity level and health status, but they have allowed its use in this clinical study.

What is the purpose of the study?

The purpose of this study is to continue to look at the safety of QBKPN SSI and the effect it has on your natural immune function, your body’s ability to resist respiratory and other infections, your body’s response to Covid-19 vaccine (if applicable), your quality of life, activity level, health status and overall survival. This study is a ‘Proof-of-Principle’ study. A Proof-of-Principle study is conducted after initial

safety testing on an experimental treatment is done. It usually involves a small number of participants (less than 100.)

Approximately 72 participants are expected to take part in the study. This study is taking place in participants' homes (for those living in the community), at approximately 8-10 independent-living, assisted-living or long-term care facilities, and at approximately 4 seniors' resource centres in British Columbia, Canada. Participants may also be recruited at the Vancouver General Hospital (VGH) / Gordon & Leslie Diamond Health Care Centre (DHCC) locations from the Infectious Diseases clinic and/or Clinical Research Unit (CRU) of the Vancouver Coastal Health Research Institute (VCHRI), through study advertisements being posted at these locations. Also, the study may be advertised in community newspapers, magazines, radio or television broadcasts, social media and special websites for people interested in participating in research studies (for example, REACH BC.)

Who can participate in this study?

You will need to meet certain requirements in order to qualify to participate in this research study. The items that will include you in this study will be reviewed with you and the study team before your participation in this study. Some of these reasons include:

- You are 65 years of age or older
- You are living in the community or a resident living in one of the independent-living, assisted-living or long-term care facilities that is participating in the study
- You voluntarily sign this Informed Consent Form
- For male participants:
    - You are surgically sterile, OR
    - If you engage in vaginal intercourse with women of childbearing potential, you agree to practice effective barrier contraception during the entire dosing period, which is 28 days, and for at least 1 month after receiving the last dose of study treatment, OR
    - You agree to not have vaginal intercourse with women of childbearing potential during your participation in the study.

Who should not participate in this study?

There may be reasons why you are not allowed to take part in this study. The study doctor or team will discuss these and any other reasons why you may not be allowed to enter the study. Some of these reasons include:

- You have a terminal illness that makes it unlikely you will live more than three months
- You are taking drugs that suppress your immune system, including high doses of prednisone or other steroid drugs (if you start taking these drugs after starting study treatment, you may be able to continue study participation)
- You are taking one or more systemic antibiotic or antiviral drugs or have taken one or more systemic antibiotic or antiviral drugs in the last 30 days, that your doctor has prescribed to treat an active infection (If you are using antibiotic or antiviral drugs that are creams, ointments or sprays you can still participate in the study)
- You have a known allergy or hypersensitivity to killed whole-cell bacterial vaccines
- You have a condition that the study doctor thinks would prevent you from study participation
- You are currently receiving an investigational treatment in another study and/or are planning treatment with a new, experimental, or investigational treatment during the course of study participation
- You are receiving treatment for an active cancer (i.e., planned cancer surgery, chemotherapy, radiation). There may be some exceptions, such as localized skin cancers and breast or prostate cancer that are controlled on hormonal therapy.

How long will I be in the Research Study?

Your total participation time is expected to be approximately 26 weeks (6 ½ months), which will include up to a 14-day screening visit, a Treatment Period (28 days) and a Monitoring Period (22 weeks).

What does the study involve?

If you are enrolled in the study, you will receive either the study treatment QBKPN SSI or placebo for the 28 days treatment period of the study. Neither you nor your study doctor/study nurses will know which treatment you are receiving, but this information is available in case of an emergency.

We are using a placebo to compare with the study treatment to make sure that the changes you report in your health, good or bad, are not due to chance. A placebo is an inactive substance, that looks like the study treatment, but which contains no treatment.

The study treatment or placebo will be given by a subcutaneous injection (i.e., just under the skin) three times a week (Monday, Wednesday, and Friday.) You will have the option of self-injecting study treatment or having study treatment injected by a study nurse during the treatment period. If you choose self-injection, the study nurse will teach you how to do this. The study nurse will stay with you for at least the first 2 doses and until you feel comfortable doing this on your own. You will be provided with a paper diary to record your self-injected doses of study treatment. No study treatment will be made available after the study ends.

Participants will be divided in 2 groups. You will be assigned by chance (like flipping a coin) to receive one of the following treatments:

Group A (48 study participants)	Group B (24 study participants)
Will receive QBKPN SSI (0.1ml) three times weekly (M-W-F) for 28 days	Will receive placebo (0.1ml) three times weekly (M-W-F) for 28 days

Twice as many participants will be assigned to receive QBKPN SSI (Group A) than placebo (Group B). You will not be able to choose which treatment group you are assigned to.

What will happen during this Research Study?

The following section breaks down what you can expect at each visit. The study nurses will visit you at your home in the community, in your independent-living, assisted-living or long-term care facility, or at a seniors' resource centre to conduct all study visits. You may also be asked to attend the Vancouver Coastal Health Research Institute Clinical Research Unit (Diamond Health Centre 2775 Laurel Street, Vancouver, BC) for study lab sampling.

The study team will be accessing your health records from your family doctor and from other doctors providing medical care for you for study related purposes.

This study consists of a screening visit, a treatment period, and a monitoring period. Description of the study procedures and tests to be performed during each of the study periods are described below.

Screening Visit/ Before you begin the study (*up to 14 days)* – 1 hour

During the screening visit, you will be asked about your medical history and any medications you have previously or are currently taking and your medical records will be reviewed.

Randomization (up to 7 days before treatment) – 30 minutes

Once the study team has determined you are eligible to participate in the study you will be chosen by chance to be placed in one of the 2 groups as described above. The study team will also review your medical history again.

Treatment Period – 28 days

Baseline Visit – 1 to 1.5 hours

Participants living in their own homes in the community will be asked to visit a participating senior community center or the VCHRI Clinical Research Unit for this Baseline visit. Before you receive your first study treatment, the following procedures will occur:

- Study team will ask you questions about your health, review your medical records, record any medication(s) that you are currently taking and discuss any changes in your health since the screening visit.
- You will have blood samples taken for standard laboratory tests and immunology tests. The amount of blood taken at this visit will be about 5-25 ml (about 1-5 teaspoons). You will also have a urine sample taken (if you are able to provide one) for standard laboratory tests.
- You will be asked to complete a quality-of-life questionnaire. (You will be asked to complete this same questionnaire at End of Treatment, Weeks 8, 12, and 26 of the study.) An example of some of the questions are “In the last week, have you felt that you are enjoying life? Have you felt sad?” You do not have to answer any questions that you are not comfortable answering.
- Your vital signs (blood pressure, heart rate, breathing rate, and body temperature), weight and height (if possible) will be measured.

Days 1 to 28 – About 30 minutes to 1 hour per visit

The study treatment is given by injection (using a small needle and syringe) three times per week (Monday, Wednesday & Friday) by the study nurse or you can choose the option of self-injection. The injection can be given under the skin in your stomach, arm, or thigh area. You will receive study treatment as outlined in the above table for Group A and B for 28 days. If you choose the self-injection option, you will be asked to complete a diary to record your self-injected doses of study treatment. The study nurse will visit you on the day following your first dose of study treatment to assess the injection site.

To avoid confusion between a possible reaction to a vaccine (for example, the flu vaccine) versus study treatment, you will not receive study treatment within 48 hours of receiving a vaccine. You can restart study treatment at your next scheduled dose.

Participants living in their own homes in the community will be asked to either visit a participating community senior center or the VCHRI Clinical Research Unit for the Baseline visit.

End of Treatment *(1 day following your last study treatment dose)*

The day following your last study treatment dose, the study nurse will visit you for your End of Treatment visit.

Participants living in their own homes in the community will be asked to either visit a participating community senior center or the VCHRI Clinical Research Unit.

During this visit, the following study procedures will occur:

- Study team will ask you questions about your health, review your medical records, record any medication(s) that you are currently taking and discuss any changes in your health since the Baseline visit.
- You will have blood samples taken for standard laboratory tests and immunology tests. The amount of blood taken at this visit will be about 25 ml (about 1-5 teaspoons). You will also have a urine sample taken (if you are able to provide one) for standard laboratory tests.
- You will be asked to complete a quality-of-life questionnaire. An example of some of the questions are “In the last week, have you felt that you are enjoying life? Have you felt sad?” You do not have to answer any questions that you are not comfortable answering.
- Your vital signs (blood pressure, heart rate, breathing rate, and body temperature) and weight will be measured.

Monitoring Period - 22 weeks - about 15 to 45 minutes per visit

When you have completed study treatment, you be monitored for 22 Weeks. The study nurse will visit you on Weeks 8, 12, and 26. The study nurse will also call you on Week 20 to ask you questions about your health and the medications you are taking.

Participants living in their own homes in the community will be asked to either visit a participating community senior center or the VCHRI Clinical Research Unit for visits at Week 8, Week 12 and Week 26.

In addition, the following study procedures will occur:

Study Procedure	Week 8	Week 12	Week 26
• You will be asked several questions about your health and the medications you are taking and your medical records will be reviewed.	✓	✓	✓
• You will have blood samples taken for standard laboratory tests and/or immunology tests. The amount of blood taken at these visits will be about 5-25 ml (1-5 teaspoons).	✓	✓	✓
• You will have a urine sample taken for standard laboratory tests (if you are able to provide one).	✓		
• Your vital signs (blood pressure, heart rate, breathing rate and temperature), and weight will be measured by the study team.	✓		

Once samples are collected from you, they will be hand delivered by study nurses or sent via courier to the Study Sponsor and/or Sponsor’s designated laboratories for analysis. These samples will only be labeled by study number, so that none of the information provided to the Sponsor will contain personal identifiers or anything that can identify who you are. Research samples may be kept at Qu Biologics for up to 5 years after the study finishes, at which time they will be destroyed according to established procedures.

Any laboratory results / data from analysis of your samples will be kept confidential by the study doctors and site study staff. However, if the tests reveal any unusual findings, your study doctor will discuss these with you, your family, and your Primary Care Provider if appropriate.

INCIDENTAL FINDINGS: During my participation in this study, there may be abnormal clinical findings identified. These findings may be important to my health, and I may benefit from having a formal clinical assessment with my family doctor and/or specialist. I agree that abnormal results from my lab samples, clinical assessment, or other research tests from this study may be communicated to my healthcare provider(s) if any clinical issues are identified that require further medical attention or follow-up.

☐ **Yes** ☐ **No** _____

Participant Initials

Data and samples collected from you as part of this study will be used solely for the purposes described in this consent document and will not be sold.

What are the possible harms and discomforts?

The study treatment is experimental, so we may not know all the discomforts, side effects and other possible risks associated with it. If you notice side effects, whatever they may be, during this research study, you must tell the study team or doctor immediately, regardless of whether you think these effects are related to the study drug.

The study team will answer any questions that you may have regarding the risks, discomforts and side effects associated with this study. Also, at each visit, the study team will ask you questions about any side effects you may have experienced.

You will find below a list of the possible side effects experienced by other participants who received the study drug.

Risks associated with the study drug QBKPN SSI

Side effects reported in participants receiving QBKPN SSI included faint redness at the injection site (about 25%) that is caused by immune activation and is an anticipated response that typically resolves within one to two days. In about 5% of participants, mild swelling or discomfort at the injection site was also experienced, in which case the dose was reduced to avoid further discomfort. About 5% of people experienced mild tiredness following the first dose, which typically resolved within a few days.

Whether you choose injection by a study nurse or self-injection, a study nurse will examine your injection site the day following the first dose.

If you develop redness at the injection site as described above, no action needs to be taken unless the redness is bigger than 7 cm across (approximately 2 ¾ inches), or is causing you discomfort that is bad enough to keep you from doing your normal daily activities. In these instances, your dose of study treatment will be reduced by half (to 0.05 ml) for the rest of the study treatment period. If you still experience redness more than 7 cm across or discomfort interfering with your normal daily activities at this lower dose, the dose will be lowered to 0.02 ml for the rest of the study treatment period. In the unlikely event that you experience redness more than 10 cm (approx. 4 inches) after an injection, your treatments will be temporarily stopped and resumed at the low dose (0.02 ml) for the rest of the study treatment period once the redness resolves. If you continue to have redness greater than 7 cm across or discomfort interfering with your daily activities at the 0.02 ml dose, your study treatment will be stopped, but you will still be allowed to participate in the study assessments.

If you choose the option of self-injection, if you notice any redness at the injection site that is more than 7 cm across (approximately 2 ¾ inches) or that is causing you discomfort which interferes with your normal daily activities after any injection of study treatment, you should contact the study nurse who will provide you with instructions on whether a dose reduction is needed.

Information for Men with Partners of Childbearing Potential

If you are a male study participant and sexually active, and if your partner(s) is/are of childbearing potential, you must inform them of your participation in a clinical drug study and the need to follow contraception instructions as directed by the study doctor. Please note that sexual partner(s) of a male study participant may be exposed to the study treatment because small amounts of study treatment may be present in semen. There is no biological reason to suspect that QBKPN SSI would cause any risk to female partners of study participants who become pregnant and/or to a fetus, but this information is not known. Therefore, if you are male and engage in vaginal intercourse with a woman of childbearing potential and she becomes pregnant, you must advise her to tell her doctor about your participation in this study.

Risks associated with Blood Draws

Blood samples will be collected during this study. A needle is inserted into a vein in your arm and a small blood sample is withdrawn. Although one needle insertion for blood draw is usually sufficient, a second one may be necessary if the first is not successful. Collecting blood samples may cause:

- Discomfort due to swelling or bruising around the injection site
- Light-headedness and fainting (uncommon)
- Very small risk of infection at the injection site

What are the potential benefits of participating?

There may not be any direct benefit to you from taking part in this study. We hope that the information learned from this study can be used in the future to benefit other people.

What are the alternatives to the study treatment?

If you choose not to participate in this study or to withdraw at a later date, you will not receive QBKPN SSI. You can discuss with your doctor before deciding whether or not to participate in this research study.

Study information and Results

If you are interested, study results will be shared with you. Study results may also be made publicly available on the Qu Biologics, Inc. website and/or published in scientific journals. Study results that are made public will not identify you in any way.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time and use the identifier NCT05421325.

What if new information becomes available that may affect my decision to participate?

If you choose to enter this study and at a later date a more effective treatment becomes available, it will be discussed with you. You will also be advised of any new information that becomes available that may affect your willingness to remain in this study. You may be invited to sign an amended consent form to indicate your continued consent to participate in the study.

After the Study is Finished

You may not be able to receive the study investigational treatment, QBKPN SSI, after your participation in the study is completed. There are several possible reasons for this, some of which are:

- QBKPN SSI may not turn out to be effective or safe.
- QBKPN SSI may not be approved for use in Canada.
- Your caregivers may not feel it is the best option for you.
- You may decide it is too expensive and insurance coverage may not be available.
- The investigational treatment, even if approved in Canada, may not be available free of charge.

What happens if I decide to withdraw my consent to participate?

You may withdraw from this study at any time without giving reasons. If you choose to enter the study and then decide to withdraw at a later time, all information about you collected up to the point of your withdrawal, including information obtained from your biological samples, will be retained for analysis in order to protect the integrity of the research, which may benefit future research participants and patients. However, no further information will be collected.

If samples have been collected before you withdraw, they will be destroyed. There may be exceptions where the samples will not be able to be withdrawn; for example, where the sample is no longer identifiable (meaning it cannot be linked in any way back to your identity).

Can I be asked to leave the study?

You may be asked to leave the study if the study doctor judges it is not in your best interest to continue, or if you are unable to fulfill the requirements for the study, or for any other reason. If you are asked to leave the study, the reasons for this will be explained to you and you will have the opportunity to ask questions about this decision. A study doctor will arrange for you to continue your care outside of the study. The study may also be stopped at any time by the Sponsor or the Research Ethics Board, Health Canada, or other applicable regulatory agencies if new information arises about the safety of the study treatment. The reasons for study stoppage will be explained to you by the study doctor or team.

How will my taking part in this study be kept confidential?

Your confidentiality will be respected. However, research, health, or other source records identifying you may be inspected in the presence of the Investigators or their designates by representatives of Qu Biologics, Inc., Health Canada, or University of British Columbia Clinical Research Ethics Board or other applicable regulatory agencies for the purpose of monitoring the research. No information or records that disclose your identity will be published without your consent, nor will any information or records that disclose your identity be removed or released without your consent unless required by law.

You will be assigned a unique study number as a participant in this study. This number will not include any personal information that could identify you (i.e., it will not include your Personal Health Number, Social Insurance Number, your initials, etc.). Only this number will be used on any research-related information collected about you during this study, so that your identity will be kept confidential. In the Sponsor's database, you will only be referred to by your study number. Your coded data and the study results may be shared with scientific journals and the scientific community.

Information that contains your identity will remain only with the Principal Investigator and/or designate. The list that matches your name to the unique study number that is used on your research-related

information will not be removed or released without your consent unless required by law. Your study doctor will keep this information, your data and your medical records for 15 years.

Some of your blood samples, labelled only with your study number but no personal information, will be stored for 5 years at the Qu Biologics, Inc. Laboratories in Burnaby, British Columbia.

Your rights to privacy are legally protected by federal and provincial laws that require safeguards to ensure that your privacy is respected. You also have the legal right of access to the information about you that has been provided to the Sponsor and, if need be, an opportunity to correct any errors in this information. Further details about these laws are available on request to your study doctor.

A copy of the consent form that you sign to enter the study may be included in your health record/facility chart.

Disclosure of Race/Ethnicity

Studies involving humans now routinely collect information on race and ethnic origin as well as other characteristics of individuals because these characteristics may influence how people respond to different medications. Providing information on your race or ethnic origin is voluntary.

Optional: I volunteer to provide my ethnicity for the purposes of this study.

☐ YES
☐ NO Participants' Initials: _____

Primary Care Physician(s) /Specialist(s) Notification

Because this is a treatment study, your signed consent form will be included in your paper or electronic medical record, and your healthcare team will be alerted that you are on a study. This is to ensure your healthcare team has a little information about the study so that they can treat you safely according to the study protocol.

Please indicate, by checking the applicable box, whether you want us to notify your primary care physician(s) or specialist(s) of your participation in this study. This is not a consent to release medical information.

☐ Yes, I want the study investigator to advise my primary care physician(s) or specialist(s) of my participation in this study. My primary care physician(s) and/or specialist(s) name(s) is/are:

_____

The name of the medical clinic I attend is: _____

Participant Initials: _____

☐ No, I do not want the study investigator to advise my primary care physician(s) or specialist(s) of my participation in this study.

Participant Initials: _____

☐ I do not have a primary care physician or specialist.

Participant Initials: _____

☐ The study investigator is my primary care physician/specialist.

Participant Initials: _____

I understand that if I choose not to advise my primary care physician(s) or specialist(s) of my participation in this study, there may be potential medical consequences which may affect my comprehensive medical care or treatment. I understand that the study investigator may not be responsible for these consequences.

You may wish to discuss the consequences of your decision with the study team.

What happens if something goes wrong?

By signing this form, you do not give up any of your legal rights and you do not release the study doctor, participating institutions, or anyone else from their legal and professional duties. If you become ill or physically injured as a result of participation in this study, medical treatment will be provided at no additional cost to you. The costs of your medical treatment will be paid by your Provincial medical plan and/or by the study Sponsor, Qu Biologics, Inc.

You will be provided with a wallet card saying that you are participating in this study. Please show it to any health care provider who takes care of you. In case of a serious medical event, please report to an emergency room and show them your study wallet card.

What will the study cost me?

All research-related medical care and treatment and any related tests that you will receive during your participation in this study will be provided at no cost to you. You will not be paid for participating in this study. However, the study Sponsor will reimburse any costs related to attending study visits (examples: parking, transportation), if you provide receipts. These reimbursements will be provided through a reloadable debit card, called a ClinCard, through a company called Greenphire. Greenphire is located in the United States but it supports clinical trials globally so has service providers in the United States and the European Union. The study team can provide you with the 'Greenphire General Data Protection Regulation Statement' which explains how your personal information is kept protected. You will need to sign the Greenphire Informed Consent Form if you choose this method. Alternatively, you can request to receive cash reimbursements per receipts provided to the study team.

If I have questions about the study procedures during my participation, who should I speak to?

If you have any questions or desire further information about this study before or during participation, or if you experience any adverse effects, you can contact the study nurse on call, 236-514-5955.

Who do I contact if I have any questions or concerns about my rights as a participant?

If you have any concerns or complaints about your rights as a research participant and/or your experiences while participating in this study, contact the Research Participant Complaint Line in the University of British Columbia Office of Research Ethics by e-mail at RSIL@ors.ubc.ca or by phone at 604-822-8598 (Toll Free: 1-877-822-8598.) Please reference the study number (H21-03956) when calling so the Complaint Line staff can better assist you.

Consent to Participate

Study Title: Assessment of QBKPN Site Specific Immunomodulator (SSI) Efficacy in Improving Innate Immune Function and Reducing All-Cause Respiratory Tract Infection Morbidity in Adults 65 Years of Age or Older Residing in the Community, in Independent-Living, Assisted-Living and Long-term Care Facilities (RESILIENCE Study)

My signature on this consent means:

- I have read and understood the participant information and consent form.
- I have had the opportunity to ask questions and have had satisfactory responses to my questions.
- I understand that participation in this study is voluntary
- I understand that I am completely free at any time to refuse participation or to withdraw from this study at any time, and that this will not change the quality of care that I receive.
- I authorize access to my health record and samples as described in this consent form.
- I authorize my family and/or treating physician to release my health record for study-related purposes
- I understand that I am not waiving any of my legal rights as a result of consenting to this study.
- I understand that the informed consent discussion may be recorded as part of documenting consent.
- I understand that there is no guarantee that this study will provide any benefits to me.
- I will be provided a Study Wallet Card providing the contact details of the study team, I shall try to carry this card with me at all times.

I have received a signed and dated copy of this consent form for my own records.

I consent to participate in this study.

The participant and the investigator or designate obtaining consent are satisfied that the information contained in this consent form was explained to and understood by the participant, that all questions have been answered, and that the participant consents to participating in the research.

_____	_____	_____
Printed Name of Participant	**Signature of Participant**	**Date** (ddMMMyyyy)

_____	_____	_____	_____
Printed Name of Investigator or Designate Obtaining Consent	**Signature of Investigator or Designate Obtaining Consent**	**Study Role**	**Date** (ddMMMyyyy)

USE OF TRANSLATORS AND/OR WITNESSES

Study Title: Assessment of QBKPN Site Specific Immunomodulator (SSI) Efficacy in Improving Innate Immune Function and Reducing All-Cause Respiratory Tract Infection Morbidity in Adults 65 Years of Age or Older Residing the Community, in Independent-Living, Assisted-Living and Long-term Care Facilities (RESILIENCE Study)

If this consent process has been done in a language other than that on this written form, with the assistance of an interpreter/translator, indicate:

Language: _____

Was the participant assisted during the consent process in one of ways listed below?

☐ Yes ☐ No [Note: For typical situations where the person conducting the consent discussion simply reads the consent with the participant to ensure that informed consent is properly obtained, check "no".]

If yes, please check the relevant box and complete the signature space below:

☐ The consent form was read to the participant, and the person signing below attests that the study was accurately explained to, and apparently understood by, the participant (please check if participant is unable to read).

☐ The person signing below acted as an interpreter/translator for the participant, during the consent process (please check if an interpreter/translator assisted during the consent process).

Printed Name of Person Assisting in the Consent Discussion	**Signature**	**Date** (ddMMMyyyy)

Optional: Greenphire Informed Consent Form

As a participant in the RESILIENCE study, you may receive reimbursement for expenses incurred to help support your participation in the clinical trial. Greenphire is a company working on behalf of the study Sponsor to support this reimbursement process. The site staff for the RESILIENCE study ('site staff') will be able to answer any questions you have about the amount or availability of payments.

For Greenphire to support this reimbursement process, Greenphire will need to process certain personal data about you. This information will be collected from you by the site staff and given to Greenphire. In addition, if you choose to not provide the required personal data, the study Sponsor will make a different method of payment available.

In the event that you decide to withdraw consent, Greenphire will assist the site staff with your request. To do so, you must contact the site staff.

Greenphire will collect and use your personal data for the following purpose(s):

- ClinCard

To issue you a Greenphire ClinCard, which is a debit card that your reimbursable funds are loaded onto when a visit is completed. The funds will be available within 1 business day. In order to assign a ClinCard to you and load funds onto the ClinCard Greenphire will need your Subject ID, Name, Address, and Date of Birth. Greenphire will retain transactional ClinCard data for at least 7 years from study close out, if there is no balance available on the card and you are not associated with any active cards.

- Email and/or Text Messaging

You will have the option to receive updates related to appointment reminders and payment alerts via text message and/or email message. Standard text messaging rates will apply. In order to send you messages Greenphire will need your: Mobile Phone Number and/or E-mail Address.

All information is transferred by the site staff to Greenphire in the United States. Greenphire has administrative, physical, and technical safeguards that reasonably and appropriately protect the confidentiality, integrity, and availability of your personal information and is ISO/EIC 27001:2013 certified. Your personal information will be used and disclosed only to support the described activities, including to service providers who assist us in managing, administering or delivering the Services. Your personal information will not be sold, used or distributed for any other purpose. Your information will be retained for as long as necessary to provide the described activities and for compliance with applicable laws.

You can exercise your rights to access, correct, modify, or delete your information at any time by contacting the site staff. If you exercise your rights or take away your consent, the site staff

will not further transfer your personal information to Greenphire, however, this may not affect processing that occurred before you took away consent.

I opt in to use GreenPhire for reimbursement purposes:

☐ Yes

☐ No

Participant's Initials _____