# Participant Information Sheet/Consent Form

**Interventional Study** - *Adult providing own consent*

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|---|---|
| **Title** | A single blind randomised controlled trial testing the effect of short-term (3 months) administration of a specialised nutritional supplement on the immune and musculoskeletal systems of older adults in aged-care |
| **Short Title** | The Pomerium Study |
| **Project Number** | HREC 2021.115 |
| **Project Sponsor** | The University of Melbourne |
| **Coordinating Principal Investigator/ Principal Investigator** | Professor Gustavo Duque |
| **Associate Investigator(s)** | Dr. Ahmed Al Saedi, Dr. Ben Kirk Dr. Sandra Iuliano, Prof. Ralph Nanan, Mrs Petra Marusic, Dr. Diana Navarro-Perez, Dr. Jesse Zanker |
| **Location** | |

## Part 1 What does my participation involve?

### 1 Introduction

You are invited to take part in this research project. This is because you are an aged care resident at a participating residential aged care facility (RACF), you are 75 years or older and may meet the inclusion criteria for participating in this study. The research project is testing a new multi-nutrient supplement which may improve immune function in older adults. The new drink supplement is called Ensure Plus Strength and is marketed in Australia by Abbott Australasia Pty Ltd. It is a specialised multi-nutrient drink which includes a combination of energy, high-quality protein, vitamin D and several other micronutrients.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the tests and the intervention involved. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or your local doctor.

Participation in this research is voluntary. If you don't wish to take part, you don't have to. You will receive the best possible care whether or not you take part.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

- Understand what you have read
- Consent to take part in the research project
- Consent to have the tests and assessments that are described
- Consent to the use of your personal and health information as described

You will be given a copy of this Participant Information and Consent Form to keep

## 2 What is the purpose of this research?

The purpose of this clinical trial is to determine whether consumption of a specialised multi-nutrient drink is associated with increased immune, muscle and respiratory function in aged care residents in response to respiratory illness such as the sessional flu and the COVID-19 virus.

Aged care residents in Victoria have been excessively impacted by the COVID-19 pandemic. Several reasons explain the increased mortality and complication rates from COVID-19 and other respiratory illnesses such as the seasonal flu in older adults. These include a decline in immune function associated with aging (known as immunosenescence), low vitamin D levels, reduced respiratory function, malnutrition and a high prevalence of frailty (defined as the decline in body functions and systems with age) to name a few. Aged care facility residents, in particular, appear to be more affected by these conditions compared to older adults who do not live in an aged care facility. Research has shown that the immune response to vaccination is diminished in the setting of immunosenescence. Therefore, it is important to boost the immune system in order to get adequate protection from vaccination.

We propose that the consumption of a specialised, commercially available, multi-nutrient drink will strengthen the immune system and reduce other risk factors associated with respiratory illness such as reduced muscle function and frailty.

This study aims to recruit approximately 160 aged care residents from participating facilities. This research has been initiated by Principal Investigator and study doctor, Professor Gustavo Duque and is supported by a team of experts in the areas of nutrition, immunology, as well as consumers and healthy ageing advocates. The project is funded by the Australian Government through the Medical Research Future Fund (MRFF) scheme which supports Australian health and medical research.

## 3 What does participation in this research involve?

The purpose of this participant information sheet is to provide you with information about the study, the initial steps, procedures or assessments and some other general information. If you decide to be involved in this study you will be asked to sign a copy of the consent from prior to any procedures or assessments taking place.

You will be participating in a randomised controlled research project. Sometimes we do not know which treatment is best for treating a condition. To find out we need to compare different treatments. We put people into groups and give each group a different treatment. The results are compared to see if one is better. To try to make sure the groups are the same, each participant is put into a group by chance (random), similar to tossing of a coin in two groups (intervention and control). Participants will be advised the group they were allocated to once randomisation is completed.

The intervention group will receive the multi-nutrient drink. The other group (or control group) will receive the usual care provided by the residential aged care facility within which they reside. This study will be conducted over a period of 6 months.

**Study structure**

This study will be conducted as follows:

**Screening (Visit 1):** During this visit, the study team will assess your eligibility to take part in the trial. Once the consent form has been signed, we will conduct the following assessments. Please note that by signing the consent form you are telling us that you have read and understood the information contained in this form.

The study team will ask you about your health and medical history, including your medication use over the past 3 months.

The following tests will be conducted:

- Your height and weight will be measured
- Your vital signs, including your blood pressure, heart rate and temperature will be recorded
- Your walking speed over 6 meters will be measured (you may use your walking aid, if required)
- Your grip strength will be measured using a device called a handheld dynamometer. You will be asked to squeeze the handle of this device to measure the strength of your grip.

Over the course of this initial evaluation, should the study team uncover any significant health findings which you may not have been aware of, your doctor will be informed who will advise what subsequent action needs to be taken.

If the study is not suitable for you, your doctor will discuss other treatment options with you and no further study procedures will be conducted.

If the study is suitable for you based on the results of the screening procedures and if you are happy to continue with study participation, you will proceed to randomisation (visit 2).

**Randomisation (Visit 2):** If you meet the "entry criteria" for the study, the following tests will be conducted during this visit:

- You will be asked about any changes to your medication schedule since visit 1
- You will be asked if you have anything new to report in terms of your overall health since visit 1
- A blood sample, non-fasting (40 ml or approximately 5 tablespoons of blood) will be collected for laboratory tests to assess your immune function and nutritional profile
- You will be asked to complete the following questionnaires:
    - Quality of life (QoL) – a standardised assessment of health-related QoL
    - Life-space mobility questionnaire – a measure of the extent of mobility of older adults
    - Nutritional assessment (MNA) – an assessment of nutritional status in elderly patients in nursing homes (amongst other settings).
- A study team member will determine your dietary intake by visual observation of your plate waste (the food that remains on your plate once you finish your meal) during two random days.
- Your lean body (muscle) mass will be measured using a bioimpedance machine; this device is similar to a conventional body weight scale.
- The following tests will be conducted:
    - Your weight will be measured

- Your vital signs, including your blood pressure, heart rate and temperature will be recorded
- A series of physical assessments will be performed; these include a balance test, a leg strength test and walking speed as previously described
- Your respiratory function will be assessed to determine how your lungs are performing. This test involves breathing into a hand held device.

**Visit 3 (Month 1):** The following assessments will be conducted during this visit:

- A blood sample (40 ml or approximately 5 tablespoons of blood) will be collected for laboratory tests to assess your immune function and nutritional profile
- You will be asked about any changes to your medication schedule since visit 2
- You will be asked if you have anything new to report in terms of your overall health since visit 2.

**Visit 4 (Month 3) or End of Intervention:** The following assessments will be conducted during this visit:

- You will be asked about any changes to your medications since visit 3
- You will be asked if you have anything new to report in terms of your overall health since visit 3.
- You will be asked to complete the following questionnaires (as previously described):

  - Quality of life (QoL)
  - Life-space mobility questionnaire
  - Nutritional assessment (MNA)

- A study team member will determine your dietary intake by visual observation of your plate waste
- Your lean body (muscle) mass will be measured using a bioimpedance machine; this device is similar to a conventional body weight scale.
- The following tests will be conducted:

  - Your weight will be measured
  - Your vital signs, including your blood pressure, heart rate and temperature will be recorded
  - A series of physical assessments will be performed; these include a balance test, a leg strength test and walking speed as previously described
  - Your respiratory function will be assessed to determine how your lungs are performing. This test involves breathing into a hand held device.

**Visit 5 (Month 6) or Follow up visit:** This final study visit will occur 3 months after ceasing the study intervention. During this visit, the study team will collect information related to the incidence of respiratory viral and/or COVID-19 infection during the study period. In addition, a blood sample (40 ml or approximately 5 tablespoons of blood) will be collected for laboratory tests to assess your immune function and nutritional profile.

**Unscheduled visit:** If at any time during the course of the study, your study doctor feels that any additional study assessments are required for medical or safety purposes an additional visit may be scheduled, assessments will be based on the reason for this visit.

The table below summarises the study visits and assessments as previously described:

**Table of Assessments**

| | Screening | Intervention | | | | Follow-up |
|---|---|---|---|---|---|---|
| **Assessment schedule** | **Screening (Visit 1)** | **Randomisation (Visit 2)** | **Month 1 (Visit 3)** | **Month 3 (Visit 4)** | **Unscheduled visit** | **Month 6 (Visit 5)** |
| Informed consent | X | | | | | |
| Medical history | X | | | | | X |
| Medication review | X | X | X | X | X | |
| Vital signs (blood pressure, heart rate & temperature) | X | X | | X | X | |
| Height | X | | | | | |
| Weight | X | X | | X | X | |
| Dietary intake | | X | | X | | |
| Walking speed test | X | | | | | |
| Handgrip strength test | X | | | X | X | |
| Physical Assessments (includes walking speed) | | X | | X | X | |
| Body composition | | X | | X | X | |
| Blood tests | | X | X | | X | X |
| Life space mobility questionnaire | | X | | X | X | |
| Nutritional questionnaire (MNA) | | X | | X | | |
| Quality of Life questionnaire | | X | | X | | |
| Respiratory function | | X | | X | X | |
| Study supplement (intervention group only) | | X | X | X | X | |
| Overall health review | | X | X | X | X | X |

There are no additional costs associated with participating in this research project, nor will you be paid. All tests and medical care required as part of the research project will be provided to you free of charge.

At the completion of the study a summary of the overall study results will be available to you. If you wish you obtain a copy of your individual results, these can also be obtained from the study team.

## 4 What do I have to do?

In order to participate in this study, it is important to inform the staff at the residential aged care facility of your desire to be involved. This study will not impact on the care you receive at your residential aged care facility. The study team will perform assessments across 5 visits as previously described. In some cases, an extra visit may be requested by your doctor. It is expected that visits 1, 2 and 4 will take approximately 1 hour each. Visits 3 and 5 will likely take up to 30 minutes each.

If you choose to participate in the study, you will not be asked to change your lifestyle habits, including your exercise regime or participation in any sporting activities. The study team will collect information on your dietary intake, but we will not request that you to change your dietary patterns during the course of the study.

Participation in the study will require you to consume the specialised multi-nutrient supplement (Ensure Plus Strength® drink) twice daily (1 bottle = 220 ml (approx. 1 cup) x 2, total intake per day 440 ml or 2 cups) for 12 weeks (if you are allocated to the intervention group). Please inform the study team of any medication that you are currently taking and if there are any changes to this medication during your participation in this project.

## 5 Other relevant information about the research project

This study will recruit 160 participants from participating residential aged care facilities. Participants will be randomly allocated to either the intervention or the control group within the same facility.

## 6 Do I have to take part in this research project?

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

If you do decide to take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your care or routine treatment, your relationship with those treating you or your relationship with the staff at your residential aged care facility.

## 7 What are the alternatives to participation?

You do not have to take part in this research project to receive treatment. Other options are available; this includes usual standard of care (consumption of the usual diet provided to you by your residential aged care facility). Your study doctor will discuss these options with you before you decide whether or not to take part in this research project. You can also discuss the options with your local doctor.

## 8 What are the possible benefits of taking part?

We cannot guarantee or promise that you will receive any benefits from participating in this research project; however, possible benefits may include an improvement in immune function which may prevent you from contracting respiratory viral infections. You will receive medical care and will be provided with blood test results and results from the remainder of the study assessments. However, despite these activities, you may not have a direct benefit from being part

of this study. Results from this study may identify the potential benefits associated with the consumption of a multi-nutrient drink in residential aged care facility residents and may lead to future changes in how viral respiratory conditions are treated.

## 9 What are the possible risks and disadvantages of taking part?

Nutritional supplements rarely cause side effects. You may have none, some of all of the effects listed below, and they may be mild, moderate or severe. If you have any of these side effects or are worried about them, talk with your study doctor. You study doctor will also be looking out for side effects.

There may be side effects that the researchers do not expect or do not know about and that may be serious. Tell your study doctor immediately about any new or unusual symptoms that you get.

Many side effects go away shortly after the intervention ends. However, sometimes side effects can be serious, long lasting or permanent. If a severe side effect or reaction occurs, your study doctor may need to stop the consumption of the drink supplement. Your study doctor will discuss the best way of managing any side effects with you.

Risks that may occur from participation on this study are possible side effects from the multi-nutrient drink or tests performed during the study.

**Side effects**

The risks associated from consuming the multi-nutrient drink are minimal and no greater than the risk of normal food consumption. The multi-nutrient drink is a commercially available product and the dose being used in this study is the same as the dose recommended by the manufacturer.

Each 220mL serve of the multi-nutrient drink contains a total of 330 kilocalories, 20 grams of protein, 1.5 grams of calcium beta-hydroxy-beta-methylbutyrate (CaHMB), 0.49 grams of calcium, 500 International Units (IUs) of Vitamin D as well as other vitamins and minerals.

Excessive vitamin D consumption can be associated with a build-up of calcium in your blood (hypercalcemia), which can cause nausea and vomiting, weakness, and frequent urination. The amount of vitamin D contained within 2 daily serves of the multi-nutrient drink is not anticipated to result in hypercalcemia however your blood calcium levels will be monitored regularly throughout the study to check for this.

<u>Unknown and Potential Risks</u>

Problems or side effects that are not currently known could also occur during this study. You will be given new information as it becomes available which can help you decide whether you wish to continue in the study.

- Your study doctor cannot predict who will or will not have side effects.
- Some side effects may go away quickly and some may last a longer time. No adverse events have previously been reported in people who have consumed the multi-nutrient drink being tested in this project.

The points below can assist you and your study doctor in treating side effects:

- Tell your study doctor if you notice or feel anything different
- Your study doctor may treat the side effect

<u>Risk associated with blood collection</u>

The procedures conducted at each visit are standard medical procedures. Blood samples will be taken from you. The risks of taking blood may include fainting, pain and/or bruising. Rarely, there may be a small blood clot or infection where the needle punctures the skin, if this happens, it can be easily treated.

Risk associated with physical tests

This study includes several physical function tests and a walking speed test. You may feel tired after these assessments, as if you have been exercising for a short amount of time. You may be at risk of falling during these measurements, so it is important to follow the study staff instructions and let them know if you need to rest between tests.

The blood pressure cuff used to assess your blood pressure may cause discomfort or bruising of the upper arm.

Risk associated with psychological distress

If you become upset or distressed as a result of your participation in the research, the study doctor will be able to arrange for counselling or other appropriate support. Any counselling or support will be provided by qualified staff who are not members of the research project team. This counselling will be provided free of charge.

**10 What will happen to my test samples?**

By consenting to take part in this study, you also consent to the collection of blood. Blood samples will be collected at the visits outlined above for laboratory analysis.

Trained personnel will collect your blood sample which will be processed and analysed at the Sunshine Hospital pathology service for routine care and in our own research laboratory for research purposes. Once samples are analysed they will be destroyed. Samples collected for research purposes will be individually de-identified with a unique code for storage. Samples will be stored until analysis is completed, then they will be destroyed.

**11 What if new information arises during this research project?**

Sometimes during the course of a research project, new information becomes available about the drink supplement that is being studied. If this happens, your study doctor will tell you about it and discuss with you whether you want to continue in the research project. If you decide to withdraw, your study doctor will make arrangements for your regular health care to continue. If you decide to continue in the research project you will be asked to sign an updated consent form.

Also, on receiving new information, your study doctor might consider it to be in your best interests to withdraw you from the research project. If this happens, he/ she will explain the reasons and arrange for your regular health care to continue.

**12 Can I have other treatments during this research project?**

Whilst you are participating in this research project, you may not be able to take some medications or treatments. It is important to tell your study doctor and the study staff about any treatments or medications you may be taking, including over-the-counter medications, vitamins or herbal remedies, acupuncture or other alternative treatments. You should also tell your study doctor about any changes to these during your participation in the research project. Your study doctor should also explain to your which treatments or medications need to be stopped for the time you are involved in the research project.

**13 What if I withdraw from this research project?**

If you decide to withdraw from the project, please notify a member of the research team before you withdraw. This notice will allow that person or the research supervisor to discuss any health risks or special requirements linked to withdrawing.

If you do withdraw your consent during the research project, the study doctor and relevant study staff will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should be aware that data collected by the sponsor up to the time you withdraw will form part of the research project results. If you do not want them to do this, you must tell them before you join the research project.

### 14 Could this research project be stopped unexpectedly?

This research project may be stopped unexpectedly for a variety of reasons. These may include reasons such as:

- Unacceptable side effects
- The multi-nutrient drink being shown not to be effective
- The multi-nutrient drink being shown to be effective and not requiring further testing
- Decisions made in the commercial interests of the sponsor or by local regulatory/health authorities

### 15 What happens when the research project ends?

Your participation in the study will conclude once all assessments are completed (conclusion of visit 5). The entire study, including all 160 participants, will take approximately 1.5 years to complete. Once all participants complete the study tasks, data will be analysed and a final report will be made available, this report will be emailed or posted to you; whichever method is more convenient in your case. The study results may be published in medical journals which are available to the public. Your identity will not be revealed in any form of communication.

## Part 2 How is the research project being conducted?

### 16 What will happen to information about me?

Any information obtained in connection with this research project that can identify you will remain confidential. Paper forms will be stored in a locked cabinet in a locked office, and electronic data will be stored in a password protected file, accessible only to investigators. Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law. By signing the consent form you consent to the study doctor and relevant research staff collecting and using personal information about you for the research project.

Information about you may be obtained from your health records held at the residential aged care facility. Your health records and any information obtained during the research project are subject to inspection (for the purpose of verifying the procedures and the data) by the relevant authorities and the institution relevant to this Participant Information Sheet. By signing the consent form you agree to the study team accessing health records if they are relevant to your participation in this research project and you authorise release of, or access to, this confidential information to the relevant study personnel and regulatory authorities.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, no identifiable information will be provided, except with your permission. The report summarising the study results will be emailed or posted to you for your information. After the consent form is signed a unique number will be allocated to you and it will be used to record your data, this unique number does not have any relationship with your personal information and therefore it cannot be used to identify you.

Information collected will be stored in a locked cabinet for 15 years, after that time period it will be destroyed. Information about your participation in this research project may be recorded in your health records.

In accordance with relevant Australian and/or Victorian privacy and other relevant laws, you have the right to request access to your information collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please contact the study team member named at the end of this document if you would like to access your information.

Any information obtained for the purpose of this research project that can identify you will be treated as confidential and securely stored. It will be disclosed only with your permission, or as required by law.

**17 Complaints and compensation**

If you suffer any injuries or complications as a result of this research project, you should contact the study team as soon as possible and you will be assisted with arranging appropriate medical treatment. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

**18 Who is organising and funding the research?**

This research project is being conducted by *The University of Melbourne* and is funded by the Australian Government through the Medical Research Future Fund (MRFF) grant scheme.

Abbott Laboratories will provide the multi-nutrient drink being studied in this project in-kind to the study investigators and may benefit financially should the study results indicate positive outcomes associated with consumption of the multi-nutrient drink.

By taking part in this research project you agree that samples of your blood (or data generated from analysis of this material) may be provided to The University of Melbourne and/or Abbott Laboratories which may directly or indirectly benefit financially from your samples or from knowledge acquired through analysis of your samples.

You will not benefit financially from your involvement in this research project even if, for example, your samples (or knowledge acquired from analysis of your samples) prove to be of commercial value to The University of Melbourne and/or Abbott Laboratories.

In addition, if knowledge acquired through this research leads to discoveries that are of commercial value to The University of Melbourne and/or Abbott Laboratories, the study doctors or their institutions, there will be no financial benefit to you or your family from these discoveries.

The University of Melbourne will not receive a payment from Abbott Laboratories for undertaking this research project.

No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

**19 Who has reviewed the research project?**

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of Melbourne Health.

This project will be carried out according to the National Statement on Ethical Conduct in Human Research (2007 and updates). This statement has been developed to protect the interests of people who agree to participate in human research studies.

**20 Further information and who to contact**

The person you may need to contact will depend on the nature of your query.

If you want any further information concerning this project or if you have any medical problems which may be related to your involvement in the project (for example, any side effects), you can contact the principal study doctor on (03) 8395 8121 or any of the following people:

**Clinical contact person**

| | |
|---|---|
| Name | Professor Gustavo Duque |
| Position | Director, Australian Institute for Musculoskeletal Science (AIMSS) |
| Telephone | (03) 8395 8121 |
| Email | gustavo.duque@unimelb.edu.au |

For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

**Complaints contact person**

| | |
|---|---|
| Name | Director Research Governance and Ethics |
| Position | Complaints Manager |
| Telephone | (03) 9342 8530 |
| Email | research@mh.org.au |

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

**Reviewing HREC approving this research and HREC Executive Officer details**

| | |
|---|---|
| Reviewing HREC name | Melbourne Health HREC |
| HREC Executive Officer | Manager HREC |
| Telephone | (03) 9342 8530 |
| Email | research@mh.org.au |

# Consent Form - *Adult providing own consent*

| | |
|---|---|
| **Title** | A single blinded, randomised controlled trial testing the effect of short-term (3 months) administration of a specialised nutritional supplement on the immune and musculoskeletal systems of older adults in aged-care |
| **Short Title** | The Pomerium Study |
| **Project Number** | HREC 2021.115 |
| **Project Sponsor** | The University of Melbourne |
| **Coordinating Principal Investigator/ Principal Investigator** | Professor Gustavo Duque |
| **Associate Investigator(s)** | Dr. Ahmed Al Saedi, Dr. Ben Kirk, Dr. Sandra Iuliano, Prof. Ralph Nanan, Mrs Petra Marusic, Dr. Diana Navarro-Perez, Dr. Jesse Zanker |
| **Location** | |

**Consent Agreement**

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to The University of Melbourne concerning my disease and treatment for the purposes of this project. I understand that such information will remain confidential.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the study without affecting my future health care.

I understand that, if I decide to discontinue the study multi-nutrient drink supplement, I may be asked to attend follow-up visits to allow collection of information regarding my health status. Alternatively, a member of the research team may request my permission to obtain access to my medical records for collection of follow-up information for the purposes of research and analysis.

I consent to the storage and use of blood samples taken from me for use, as described in the relevant section of the Participant Information Sheet, for:

- This specific research project

I understand that I will be given a signed copy of this document to keep.

**Declaration by Participant – for participants who have read the information**

Name of Participant (please print) _____

Signature _____ Date _____

Declaration - for participants unable to read the information and consent form
See Note for Guidance on Good Clinical Practice CPMP/ICH/135/95 Section 4.8.9. A legally acceptable representative may be a witness*.
Witness to the informed consent process
Name (please print) _____

Signature _____ Date _____
* Witness is not to be the Investigator, a member of the study team or their delegate. Witness must be 18 years or older.

**Declaration by Study Doctor/Senior Researcher†**
I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Name of Study Doctor/
Senior Researcher† (please print) _____

Signature _____ Date _____

† A senior member of the research team must provide the explanation of, and information concerning, the research project.
Note: All parties signing the consent section must date their own signature.

# Form for Withdrawal of Participation - *Adult providing own consent*

| | |
|---|---|
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| **Location** | |

**Declaration by Participant**

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine treatment, my relationship with those treating me or my relationship with the Residential Aged Care Facility

Name of Participant (please print) _____

Signature _____ Date _____

**Declaration by Study Doctor/Senior Researcher†**

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the participant has understood that explanation.

Name of Study Doctor/
Senior Researcher† (please print) _____

Signature _____ Date _____

† A senior member of the research team must provide the explanation of and information concerning withdrawal from the research project.

Note: All parties signing the consent section must date their own signature.