Patient and Study Partner Information Sheet v1.0
NRES Committee London Hampstead – Ref 14/LO/1510

PROTOCOL NUMBER: SILADv1.0

Sponsor: University of Southampton  Principal Investigator: Clive Holmes

Participant Initials:  Participant Number:

Study title: Systemic inflammation in Dementia with Lewy Bodies and Alzheimer’s Disease (SILAD)

Lay title: The role of the immune system in people with Lewy Body Dementia and Alzheimer’s Disease

Introduction
You are being invited to take part in a research study being conducted at the Memory Assessment and Research Centre.

Participation in this study is voluntary. This means you are free to decide whether or not to take part in this research study.

You may need someone (such as a relative or close friend) to participate in this study with you. We will call them your ‘study partner’ in this information sheet.

Before you decide to take part, it is important that you understand why the research is being done and what it will involve. This form describes:

• The known possible risks and benefits of participating in this study.

• The procedures you will be asked to complete if you take part in the study.

• The study responsibilities for you and your study partner.

• The choices for your care if you decide not to be in the study.

Please take your time to read the following information. Discuss it with your friends and family if you wish.
If you wish to be in the study then you and your study partner will be asked to sign and date the Patient and Study Partner Informed Consent Form. A copy of the signed Informed Consent Form will be provided to you.

Thank you for taking the time to read this information. Please ask the study staff any questions you may have.

**Who is organising and funding the study?**

The study is being organised by Professor Clive Holmes at the Memory Assessment and Research Centre. Tel: 023 8047 5206.

The University of Southampton is the sponsor for this study. The study is funded by Alzheimer’s Research UK.

**What is the purpose of the study?**

The purpose of the study is to find out more information about the role of the immune system in people diagnosed with Lewy Body Dementia and Alzheimer’s Disease and how it may differ from people without a memory disorder.

Many of the symptoms of Lewy Body Dementia and Alzheimer’s disease also occur when people suffer with delirium, a condition which some elderly people get when they have an infection. The immune system in Alzheimer’s Disease and Lewy Body Dementia has not been well researched but we think that the condition is caused, or made worse, by an overactive immune system which makes it look like an infection is taking place.

We want to see if this is the case and if we can prove it we will be in a much better position to develop new treatments. We also think our research could help allow us to develop a blood test for the disease that means Doctors can diagnose the conditions earlier.

**Why have I been chosen?**

Study staff have invited you to participate in this study because you have been diagnosed with either Dementia with Lewy Bodies or Alzheimer’s disease, or because you do not have a diagnosis of Dementia.

By participating in this study, you may help create knowledge that could help improve the diagnosis and treatment for people with Dementia with Lewy Bodies and Alzheimer’s disease in the future, but this cannot be guaranteed.

120 volunteers will participate in this study which will be carried out at the Memory Assessment and Research Centre Memory Assessment and Research Centre, Tom Rudd Unit, Moorgreen, Botley Road, West End, Southampton, SO30 3JB, United Kingdom.
What are my responsibilities while I am in the study?

- We ask that you please keep your one-off study appointment and have your study partner attend with you if needed. If you cannot keep your appointment please contact us to reschedule.
- Please allow the trained study researcher or doctor to carry out a blood test at the time of your visit.
- Please tell us if you change your mind about staying in the study.
- Please feel free to ask us any questions you think about.

Whilst you are in this study we ask that you do not take part in any other research study. This is because other studies may affect this study.

What are the responsibilities of the study partner in the study?

Your study partner is a close friend or relative who knows you well or is the main person that helps you with your daily activities. If you have been diagnosed with Alzheimer’s Disease or Dementia with Lewy Bodies we ask that this person is present at the study appointment as your study partner’s information about you is an important part of the study.

- They will be asked to sign a consent form for their own involvement with the study.
- They will be asked questions about your symptoms and about your past medical history.
- They will be asked to inform us if you are unwell, or develop new symptoms, if you are unable to let us know yourself.

What will happen to me if I take part?

If you decide to participate, study staff will ask to visit you in your own home or at the Memory Assessment and Research Centre for a single visit. A brief description of what will happen to you at the visit is reported below.

**Single visit**
Study staff will ask to visit you in your own home or if you prefer at the Memory Assessment and Research Centre. At this visit you will be provided with information about what the study entails. If you and your study partner are still willing to take part, you will be asked to give consent for participating in the study. The study staff will then ask you a series of questions about your health and what medications you take.

You will be asked to complete a range of tests to assess your memory and thinking ability. You will also be asked to complete some brief questionnaires that ask questions about your mood.
The study staff will ask to carry out a blood test with you (30.5ml, which is approximately 2 tablespoons of blood).

Your study partner will be asked to perform some assessments. These assessments will measure your mood and level of thinking ability.

The whole visit will take approximately 2-3 hours to complete.

**Biological samples**

At the one-off study visit, taking place at your home or the study centre if you prefer, the research staff will ask to carry out a blood test with you. A total of 30.5ml (which is approximately 2 tablespoons) of blood will be taken. Usually all blood samples are taken at the same time, which means you should not get an extra needle prick.

With your consent we would like to perform a blood test to look at possible genetic risk factors that may be related to memory impairment. We want to find out if genes affect your memory. This genetic information about you will stay private and confidential and will not be given to you or your doctor.

We would also like to use the blood samples to investigate the blood cells that work as part of your immune system. We want to test these immune cells in laboratory experiments to research the way they react to certain conditions. We want to find out if the immune cells in people with your condition react in a common way.

**What will happen to any samples that I give?**

Blood samples will be analyzed by the local laboratory at Southampton General Hospital. The samples will be stored in a safe location and will not be labeled with any information that would identify you directly. A participant number that is linked to your information will be used instead.

The University of Southampton will ask for your permission to store some samples of blood for possible future research related to Dementia with Lewy Bodies and Alzheimer’s disease. These stored samples will keep your patient identification number and will be stored for a maximum of 8 years after the end of the study. Any sample remaining at that time will be destroyed safely and securely.

If you decide to withdraw from the study for any reason, you can request that the samples you have given are destroyed safely and securely.
Early withdrawal from the study

The entire study could be discontinued at any time by the following entities: study doctors, the Ethics Committee or the Southern Health NHS Foundation Trust if the safety of research participants is found to be at too much risk.

What will happen if I don’t want to carry on with the study?

You may decide to stop participating in the study at any time without giving any reason. A decision to withdraw will not affect the care you receive. If you decide to withdraw, please tell the study staff. The study staff will discuss with you the best way to stop your participation in this study.

Your study doctor or the study sponsor may take you out of the study if they think it is in your best interests or if you do not follow the study instructions.

Do I have to take part?

It is up to you to decide if you want to take part in this study or not.

- If you do decide to take part, we will give you a copy of this information sheet and we will ask you to sign a consent form.
- If you decide not to take part, it will not make any difference to your present or future medical care.
- You are still free to change your mind later and withdraw from the study at any time without giving a reason. Again, it will not make any difference to your present or future medical care.

If you decide to participate, you will be told of any important new information that is learned during the course of this research study that might affect your condition or your willingness to remain in the study.

Your ability to consent

It is important that you are able to give informed consent in order to participate in this study. By this we mean that you fully understand what the study is about and what will happen to you during the study whilst you are taking part. If your condition deteriorates and you are no longer able to give informed consent during the study, you and your study partner’s participation will be stopped immediately with no further study procedures carried out.

What are the possible risks / discomforts of the procedures or tests?

During your study visit, research staff will ask to take a blood sample from you. The risks of drawing blood include temporary discomfort from the needle in your
arm, bruising, swelling at the needle site, and, in rare instances, infection. You may also experience nervousness, tiredness or boredom during the mental testing at your visit.

You are free to stop any test or procedure at any time.

Please report immediately any unusual symptom you may experience during the course of the study to the study staff.

What are the possible benefits of taking part?

This study may not have a direct benefit for you, but you may feel satisfaction in knowing that your participation in this study may help create knowledge that could help improve the diagnosis and treatment for people with Dementia with Lewy Bodies and Alzheimer’s disease in the future, but this cannot be guaranteed.

What if something goes wrong?

The Southern Health NHS Foundation Trust and the University of Southampton provides insurance in case you are injured or become ill as a result of taking part in this study. If you think you have become hurt or sick as a direct result from the study, please contact the Memory Assessment and Research Centre on 023 8047 5206.

In the event that your participation in this study results in a medical problem your doctor will explain the treatment options available and where you can go to get information and be treated.

If you are not happy with the general care and treatment you receive during the study, please speak first to the study staff, who will try to resolve the problem. They will also tell you about the research clinic’s standard complaints procedure in case you wish to take the matter further. Further information on your rights as a research participant and on the complaints procedure can also be provided by Southern Health NHS Foundation Trust Complaints and PALs Team. Address: FREEPOST RSJL-JXSX-ATUE, Complaints and PALs Team, 5 Sterne Road, Tatchbury Mount, Calmore, Southampton, SO40 2RZ, and Tel: 02380 874065.

What are the alternatives for diagnosis or treatment?

You do not have to take part in this study to receive the NHS standard care available for patients diagnosed Dementia with Lewy Bodies or Alzheimer’s disease.

Your participation in this study is voluntary and does not affect your rights or the care given to you. If you choose not to participate in this study, or if you withdraw your consent at any time throughout the study, you will continue to receive care for your condition as usual.
Who has reviewed the study?

All research in the NHS is reviewed by an independent group of people, called a Research Ethics Committee, to protect your safety, rights, wellbeing and dignity. This study has been considered and given a favourable opinion by the NRES Committee London Hampstead – Ref 14/LO/1510.

Will my records be kept confidential?

Every effort will be made to keep all information about you private. As far as possible, all of your study records will show only your initials instead of your name. Your medical records will be checked in the clinic and will not be removed from the clinic. To protect the identity of your data, you will be assigned a unique participation number with which your data will be coded in the study database.

If you decide to take part, it will be necessary for qualified members of the NRES Ethics Committee, the sponsor, and applicable regulatory authorities to have access to your medical records to check that the information from the study has been recorded accurately. By signing the consent form, you are giving permission for this to happen. In the event of the study results being sent to regulatory authorities, or published, all your records will be kept confidential, and your name will not be disclosed to anyone outside the clinic. Information that identifies you will be kept confidential unless law requires disclosure. Absolute confidentiality cannot be guaranteed because of the need to provide information as described above.

If you decide to take part in this research study, your authorisation for this study will not expire unless you revoke it. If you do withdraw from this study, the information you have already provided will be kept confidential. It is your right to obtain information on what is recorded about you and request corrections of errors.

With your consent we will notify your General Practitioner (GP) about your participation in this study.

What will happen to the results of the research study?

The data held for you relating to this study will be accessed by the University of Southampton. We will report the study and the results, submit the results to regulatory authorities, and may publish it in a scientific journal. If the results are published, or are presented at scientific meetings, your identity will not be revealed.

The University of Southampton may combine the health information obtained from participants’ study records from this and other research studies. The information will be kept in a database and used for further research purposes. All participant information that is collected from you as a result of your
participation in this study will be de-identified (anonymous), which means that you will not be directly identified and the information cannot be linked to a specific study participant.

**Expenses and payments**

There will be no additional cost to you as a result of being in the study. It is important that you understand that you are not being paid to be a participant in this study. However, you will be reimbursed for your costs of being in this study.

**Contact Details:**

If you have any questions about this study or a research-related problem, please contact your study doctor at:

Professor Clive Holmes or Dr Jay Amin  
Memory Assessment and Research Centre  
Tom Rudd Unit  
Moorgreen  
Botley Road  
West End  
Southampton  
SO30 3JB  
Tel: 023 8047 5206
Patient and Study Partner Consent Forms v1.00
NRES Committee London Hampstead – Ref 14/LO/1510

<table>
<thead>
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### Study Patient Consent Form

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<tbody>
<tr>
<td>1</td>
<td>I confirm I have read and understand the information sheet dated [ ] version [ ] (or someone has read it to me) for the above study. I understand that my participation is voluntary and that I am free to withdraw at any time without my medical care or legal rights being affected. I will get a signed copy of this form for my records.</td>
</tr>
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<td>2</td>
<td>The study researcher has answered my questions in a way that makes sense to me. I have had time to consider taking part in this study.</td>
</tr>
<tr>
<td>3</td>
<td>I understand that relevant sections of my medical records and data collected during the study may be looked at by individuals from the sponsor for this study, from UK regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records, providing strict confidentiality is maintained.</td>
</tr>
<tr>
<td>4</td>
<td>I voluntarily agree to allow study staff to collect, use and share my health data. I understand that I am not giving up any of my legal rights by signing this form.</td>
</tr>
<tr>
<td>5</td>
<td>I voluntarily agree to allow study staff to collect a blood sample from me.</td>
</tr>
<tr>
<td>6</td>
<td>I understand that the storage of blood samples for future research is entirely optional.</td>
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7. I agree that the blood samples I have given and the information gathered about me can be stored by the University of Southampton for possible use in future research projects.

8. I agree for genetic testing to be performed on my blood samples.

9. I agree for my study partner to provide information about my mood, behaviour and level of thinking ability.

10. I agree to complete questionnaires that assess my mood and behaviour.

11. I agree to perform tests which assess my memory and thinking ability.

12. I understand that I am free to stop any assessment, test or questionnaire at any time. I understand that I do not have to answer study questions or provide a reason to study staff for refusing to answer a question.

13. I agree to my GP being informed of my participation in the study.

14. I understand that if I am no longer able to fully consent to my involvement in this study that mine and my study partner’s participation will be stopped immediately with no further study procedures carried out.

15. I agree to take part in the above study.

**PATIENT**

Print name: _____________________________________________

Signature: _____________________________________________

Date: _______________________________________________________________________

INVESTIGATOR

- I have carefully explained to both the patient and the study partner the nature and purpose of the above study.
- There has been an opportunity for both the patient and the study partner to ask questions about this research study.
- I have answered all questions that the patient and study partner have about this study.

Print name: _____________________________________________

Signature: _____________________________________________

Date: _______________________________________________________________________

NRES Committee London Hampstead – Ref 14/LO/1510
SILAD
Version 1.0 – 16th July 2014
### Patient and Study Partner Consent Forms v1.00

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#### Study Partner Consent Form

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<td>2</td>
<td>I have had the time to consider taking part, have had the opportunity to ask questions, and these questions have been answered in a way that makes sense to me.</td>
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<td>3</td>
<td>I confirm that I am in regular contact with the patient.</td>
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<td>4</td>
<td>I agree to provide information about the patient’s mood, behaviour and thinking ability.</td>
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<tr>
<td>6</td>
<td>I understand that if I cannot fulfil the study responsibilities I should let the study staff know. I understand that I may be asked to find someone else to take over these responsibilities for the time that I am unavailable.</td>
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NRES Committee London Hampstead – Ref 14/LO/1510
SILAD
Version 1.0 – 16th July 2014
7. I will endeavour to ensure that the patient will attend the required visit, but will not force the patient to attend. Should the patient become unwilling to attend the study visit I will inform study staff. I will try to accompany the patient at the study visit.

8. I understand that if the patient is unable to give ongoing informed consent to participate in the study that mine and the patient’s participation will be stopped immediately with no further study procedures carried out.

9. I agree to participate in this study, to attend the study visit and to provide information on how the patient is doing.

**STUDY PARTNER**

Print name: _____________________________________________

Signature: _____________________________________________

Date: _________________________________________________

**INVESTIGATOR**

- I have carefully explained to both the patient and the study partner the nature and purpose of the above study.
- There has been an opportunity for both the patient and the study partner to ask questions about this research study.
- I have answered all questions that the patient and study partner have about this study.

Print name: _____________________________________________

Signature: _____________________________________________

Date: _________________________________________________
Control Subject Consent Form v1.00
NRES Committee London Hampstead – Ref 14/LO/1510

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Control Subject Consent Form

1. I confirm I have read and understand the information sheet dated __________ version ____ (or someone has read it to me) for the above study. I understand that my participation is voluntary and that I am free to withdraw at any time without my medical care or legal rights being affected. I will get a signed copy of this form for my records.

2. The study researcher has answered my questions in a way that makes sense to me. I have had time to consider taking part in this study.

3. I understand that relevant sections of my medical records and data collected during the study may be looked at by individuals from the sponsor for this study, from UK regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records, providing strict confidentiality is maintained.

4. I voluntarily agree to allow study staff to collect, use and share my health data. I understand that I am not giving up any of my legal rights by signing this form.

5. I voluntarily agree to allow study staff to collect a blood sample from me.
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<td>I agree to take part in the above study.</td>
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**SUBJECT**

Print name: _____________________________________________

Signature: _____________________________________________

Date: _____________________________________________

**INVESTIGATOR**

- I have carefully explained to the control subject the nature and purpose of the above study.
- There has been an opportunity for the control subject to ask questions about this research study.
- I have answered all questions that the control subject has asked about this study.

Print name: _____________________________________________

Signature: _____________________________________________

Date: _____________________________________________