45 Queen Anne Street, London, W1G 9JF
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Pre-screening Participant Information Sheet

Study Title: A PHASE 3, MULTICENTER, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED STUDY OF THE EFFICACY, SAFETY AND BIOMARKER EFFECTS OF ALZ-801 IN SUBJECTS WITH EARLY ALZHEIMER'S DISEASE AND APOE4/4 GENOTYPE

Protocol Number:	ALZ-801-AD301 (APOLLOE4)
Sponsor:	Alzheon, Inc., 111 Speen Street, Suite 306, Framingham, MA 01701 USA
Research Site	Re:Cognition Health, 45 Queen Anne Street, London, W1G 9JF
Principal Investigator:	Dr. Emer MacSweeney, 45 Queen Anne Street, W1G 9JF, 020 3355 3536
IRAS Project ID:	295043

You are being invited to take part in the "pre-screening" evaluation for potential participation in a research study because you may have early stage Alzheimer's disease (AD).

It is entirely up to you to decide if you want to take part. Before you decide, it is important for you to understand why the pre-screening is being carried out and what it will involve for you. No one can make you take part in the pre-screening evaluation if you do not wish to. The study doctor will respect your decision even if others (your caregiver or your study partner, your legal representative, your doctor, etc.) want you to participate.

The study doctor or a member of our study team will go through this information sheet with you and explain the study to you. Please read the following information carefully and ask any questions you have. If you wish you can discuss your taking part in this study with your friends, family and/or your GP. You can take as much time as you like to make your decision.

Please note that to take part in the pre-screening evaluation, you will also need to have a care giver or study partner (referred to as "caregiver" throughout this document) who is willing to support you and come to this visit with you. This may be your partner, a relative or friend, (who you see at least 10 hours per week).

Note for the Legal representative, if applicable:

We are providing you with this document to read to guarantee the patient's rights. You are being invited to consider giving your permission as the patient`s legal representative for him/her to take part in this research study. Before you decide it is important for you to understand why the research is being done and what it will involve. We would then ask that you consider what the wishes of the patient would have been, had they been able to consent for themselves. Please take time to read the following information

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carefully and discuss it with others if you wish. Please ask the patient's study doctor if there is anything that is not clear or if you would like more information. Thank you for reading this.

Please note that for the remainder of this document "you" is referring to the patient.

1. What is the purpose of the pre-screening evaluation?

The purpose of this pre-screening evaluation is to find out if you may be eligible for the screening phase of the main study ALZ-801-AD301. One of the requirements is to have AD with two copies of the APOE4 gene. The pre-screening testing will be done to determine if you have two copies of the APOE4 gene (i.e., that you have the APOE4/4 genotype).

If the results from this pre-screening evaluation show that you are eligible for the screening phase of the main study ALZ-801-AD301, you will be provided with detailed information about it. At that time, you will be asked to sign a separate informed consent document in order to take part in the main study.

2. Do I have to take part?

Taking part in this pre-screening evaluation is voluntary and entirely up to you. If you choose to take part, you will need to sign and date the consent form. You will receive a copy of this information sheet and the signed and dated consent form to keep.

You can decide not to participate or change your mind at any time. It will not affect your medical care or prevent you from receiving any benefits to which you are entitled.

If you do not take part in the pre-screening evaluation, you cannot take part in the main study.

3. How long will I be in the pre-screening evaluation?

You will have one visit or more at the study site to complete the pre-screening evaluation. The pre-screening evaluation will take approximately 1 hour. This visit will occur up to 77 days prior to the main study.

4. How many people will be in the pre-screening evaluation?

As many as 3000 potential participants at approximately 85 sites in North America and Europe may need to take part in the pre-screening evaluation. About 300 participants may ultimately be eligible for and enter the main study. There is a limit to the number of people that can take part in the main study. Once that number of people is reached, further new pre-screening will be stopped. If you are already in the pre-screening stage when this happens, and you are suitable for the study, you will be allowed to go into the next screening stage of the study and receive treatment with study medicine if you are still suitable for the study.

5. Study treatment

This document is only about the pre-screening evaluation, which does not involve any study treatment. However, to help you understand if you want to take part in this required pre-screening evaluation for the main study, the study staff will explain the main study to you in more detail. Briefly, the main study involves an investigational medicine called ALZ-801 for people with AD and the APOE4/4 genotype. ALZ-801

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could slow down or stop the worsening of AD. “Investigational” means that ALZ-801 is not approved for treatment of AD by regulatory authorities in any country.

If you are eligible for the main study after the prescreening and screening evaluations, you will be assigned randomly (by chance, like flipping a coin) to receive either ALZ-801 or placebo. A placebo looks identical to the study medicine but does not contain any active medicine.

You will have a 50% (1 in 2) chance of receiving ALZ-801, and a 50% (1 in 2) chance of receiving placebo.

Neither you nor your study doctor can choose which treatment you will receive.

6. What will happen during the pre-screening evaluation?

If you decide to take part in the pre-screening evaluation and after you sign the informed consent form, the following tests and evaluations will be done:

- You will be asked to provide some basic demographic information (your age, gender, race and/or ethnicity).
- The study doctor will review your medical history including, but not limited to, prior therapies, other illnesses, and surgeries. This may require a review of your medical records.
- You will be asked about all medications you are taking or have taken. For some medications, at least a certain period of time must have passed since the medication was stopped (the washout period). The study doctor will provide you with more information about this. If you do not qualify for the pre-screening visit due to the washout period not being satisfied, you can undergo the pre-screening visit later.
- You will undergo a test to evaluate your mental health.
- A blood sample will be collected for the APOE4/4 genotype test.

7. Biological sample

This pre-screening evaluation involves the collection of a blood sample (10 mL/2 teaspoons). This sample will be used for a genetic test to determine whether you have the APOE4/4 genotype.

Your sample will be shipped to an accredited central laboratory and tested for APOE genotype. You must have the APOE4/4 genotype to continue to the screening phase of the main study.

The central laboratory being used in this study is ICON Clinical Research Ltd, USA

With your consent, your leftover sample may be stored for a possible future analysis of AD-related proteins (called biomarkers). This AD biomarker research may help other individuals with your genotype.

8. What do I have to do?

- Provide accurate and complete information about your medical history and your present conditions.
- Tell the study team about all medications you are taking or have taken.

9. What are the risks and possible discomforts of being in this pre-screening evaluation?

Blood collection: Obtaining blood from a vein may sometimes cause pain and bruising at the site where the blood is drawn, and occasionally light-headedness and rarely, fainting. Taking a blood sample does

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not generally carry any serious risk. Very rarely, there may be some inflammation of the vein, formation of a blood clot, or permanent nerve injury.

Genetic research risk: This research involves your genetic material and personal information. Although no one can guarantee absolute confidentiality when genetic material is involved, or that your identity will never become known, several steps and procedures have been put in place to make it very difficult for the results from this genetic research to be linked to you. Even without your name or identifiers, genetic information is unique to you, making it possible for someone to trace it back to you. The results of genetic research may also reveal information about your family members. Genetic information could be used in ways that could cause you or your family distress.

There may be risks that at this time are unknown. As technology advances, there may be new ways of linking information back to you that we cannot foresee now. If new risks are identified your study doctor will tell you about them in a timely manner and discuss with you whether you wish to continue participating in this research. If you decide to continue you may be asked to sign an updated consent form.

10. Benefits

There is no direct benefit to you from taking part in this pre-screening evaluation.

11. What are the costs of taking part?

There are no costs for you if you take part. You will not be charged for any pre-screening evaluation related procedures.

Any reasonable journey costs (cost of fuel, bus or railway tickets) and subsistence costs will be reimbursed to you, provided they are supported by valid receipts.

As a participant in the ALZ-801-AD301 (APOLLOE4) study, you may receive reimbursement for expenses incurred to help support your participation in the study. Greenphire is a company working on behalf of Alzheon, Inc. to support this reimbursement process. The site staff from the ALZ-801-AD301 (APOLLOE4) study 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 from the ALZ-801-AD301 (APOLLOE4) study and given to Greenphire. In addition, If you choose not to provide the required personal data, Alzheon, Inc. will make a different method of payment available.

In the event that you decide to withdraw consent, you should inform your study doctor. Your study doctor will inform Alzheon of your decision to withdraw your consent and Greenphire will assist Alzheon with your request.

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 of your site visit. In order to assign a ClinCard to you and load funds onto the ClinCard Greenphire will need your Participant 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 is not associated with any active cards.

Study-Related Travel

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For approved travel, you or the site staff from the ALZ-801-AD301 (APOLLOE4) study will be required to book your travel arrangements through Greenphire's Travel Vendor, and the costs for such travel arrangements will be paid directly by the study. In order to book travel and provide you with itineraries, Greenphire and the Travel Vendor will need your: Name, Address, Date of Birth and E-mail. Additional information may be required by the Travel Vendor to complete the booking.

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 from the ALZ-801-AD301 (APOLLOE4) study. 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.

You will not receive any <other> payment for taking part in this pre-screening evaluation.

12. What if there is an injury during the study?

Complaints

If you have a concern about any aspect of this study, you should speak to the researchers who will do their best to answer your questions 020 3355 3436. If you remain unhappy and wish to complain formally, you can do this by contacting Re:Cognition Health Compliance Team. Details can be obtained from compliance@re-cognitionhealth.com.

Harm

We will provide compensation for any injury caused by taking part in this study in accordance with the guidelines of the *Association of the British Pharmaceutical Industry (ABPI).* We will pay compensation where the injury probably resulted from a drug being tested or administered as part of the study protocol or any test or procedure you received as part of the study.

Any payment will be without legal commitment (please ask if you wish for more information on this).

We would not be bound by these guidelines to pay compensation where the injury resulted from a drug or procedure outside the study protocol or the protocol was not followed.

If you are ill or injured as a direct result of being a participant in this study, Alzheon, Inc., the study Sponsor, will provide payment for your out-of-pocket expenses necessary to treat your injury which are not covered by your health insurance or government program if:

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•The study doctor and study staff followed all of the study procedures according to the study protocol.

This agreement to provide payment for medical expenses does not include costs for treatment of an illness or injury that is not a direct result of the study procedures. No funds have been set aside to compensate you for such illnesses or injuries. In addition, no funds have been set aside to compensate you for non-direct damages, such as lost wages, disability, or discomfort due to any research-related illness or injury. Signing this consent form does not waive or change any legal rights you may have. For instance, your legal right to claim compensation for injury where you can prove negligence is not affected by signing this form.

If you think that you have experienced an injury caused by the study procedures, you should get immediate medical help and let the health care provider know you are in a research study. Also, contact the study doctor as soon as possible.

13. Confidentiality and Data Protection

How will we use information about you?

We will need to use information from you, your medical records, possibly from your GP (if you agree) and this research project.

This information will include your initials, name, year of birth, age, race, ethnic origin, gender, health and medication usage. People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure.

Some of your information will be sent to countries outside the United Kingdom. They must follow our rules about keeping your information safe.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- If you choose to stop taking part in the study, we would like to continue collecting information about your health from your hospital. If you do not want this to happen, tell us and we will stop.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.
- If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study. Samples for future research will be stored at ICON Laboratory Services, Inc., Ireland and USA.

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Where can you find out more about how your information is used?

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- by asking one of the research team
- by sending an email to dataprivacyoffice@alzheon.com or

Retention

The sponsor will retain your pre-screening evaluation data for at least 25 years in accordance with clinical trial rules. The retention time may be longer if your study data is included in filings used to obtain approvals.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov and https://www.clinicaltrialsregister.eu/. These websites will not include information that can identify you. At most, the website will include a summary of the results. You can search these websites at any time.

14. Funding and contact information

The pharmaceutical company Alzheon, inc., has designed and is funding this clinical study. Funding for this study will also come from the US National Institute on Aging. Your hospital or study doctor will be paid for supervising your participation and treatment in this study.

To protect your safety, rights, wellbeing and dignity, all research is reviewed by an independent group of people called an ethics committee. This study has been given a favourable opinion by Wales Research Ethic Committee 5..

If you have any questions or concerns about the research or your rights as a participant, or any injury or you are unwell, please contact the study doctor <or the study coordinator/nurse>.

Dr. Emer MacSweeney	Coordinator Lorna Beston
Phone No. 020 3355 3536	Phone No. 020 3355 3536
Address 45 Queen Anne Street, London	lbeston@re-cognitionhealth.com
emacsweeney@re-cognitionhealth.com	

Thank you for reading this Information Sheet.

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Informed Consent Form

Study Title: A PHASE 3, MULTICENTER, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED STUDY OF THE EFFICACY, SAFETY AND BIOMARKER EFFECTS OF ALZ-801 IN SUBJECTS WITH EARLY ALZHEIMER'S DISEASE AND APOE4/4 GENOTYPE

Protocol Number: ALZ-801-AD301 (APOLLOE4)

Sponsor: Alzheon, Inc.

Research Site Re:Cognition Health, 45 Queen Anne Street, London, W1G 9JF

Principal Investigator: Dr. Emer MacSweeney

IRAS Project ID: 295043

Patient ID:

The participant should complete the following:	Please initial
1. I confirm that I have read and understand the information sheet (version 2.0, dated 28Apr2021) for the pre-screening evaluation.	☐
2. I confirm that the pre-screening evaluation has been explained to me and I have had the opportunity to ask questions and ample time to decide whether to participate. I know whom to contact if I have any further questions.	☐
3. I understand that relevant sections of my medical records will be reviewed by representatives of the sponsor, auditors and national and foreign regulatory authorities where it is relevant to my taking part in the study. I give permission for these individuals to have access to my medical records.	☐
4. I consent to the processing of my personal data, including health data, genetic and other data for the purposes of the study as described in section "Confidentiality and Data Protection" of the information sheet.	☐
5. I agree to the transfer of my study related data including year of birth, age, race, ethnic origin, gender, information about my health and medication usage to the sponsor and to regulatory authorities both within and outside the United Kingdom. I understand that my personal data identified only by my SID number may be sent to countries that do not have the same level of data protection as the United Kingdom.	☐
6. I agree that my pre-screening evaluation related data identified only by my SID number can be archived.	☐
7. I agree that a blood sample collected from me can be used for the purposes of this pre-screening APOE genotyping evaluation.	☐
8. I agree to take part in this pre-screening evaluation.	☐
9. I agree that my GP can be informed of my participation in this study	☐
10. OPTIONAL: I agree to the use of Greenphire for patient reimbursements	☐

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A copy of the information sheet and your signed and dated consent form will be given to you to keep.

Signature of participant Date of Signature

Printed name of participant (CAPITALS)

I have fully informed the participant about the study. The participant has been given the opportunity to ask questions and ample time to decide whether or not to participate:

Signature of investigator/person conducting the informed consent discussion Date of Signature

Printed name of investigator/person conducting the informed consent discussion (CAPITALS)

Please note:

*If an adult participant can't read and/or write or is unable to use his extremities to sign, he/she only requires an impartial witness. Only participants who are **assessed** unable to give informed consent for physical or mental reasons require a Legal Representative (CTIMP).*

In support of a participant unable to consent who still is able to assent:

By crossing this box, I express my willingness to participate in this study: ☐

Investigator

(Applicable if involvement of adults partially or not able to consent themselves).

I confirm that the above participant has been assessed as:

- *partially capable to understand all aspects of this research study*

Yes ***No*** *(please circle)*

- *not capable to understand all aspects of this research study*

Yes ***No*** *(please circle)*

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If partially capable, the participant might cross the above box to express his/her assent to participate, in line with the consent of his/her Legal Representative (person defined as per local regulations).

The caregiver/study partner signature section should be completed if the caregiver/study partner is different from the legally acceptable representative.

Signature of caregiver/study partner Date of Signature

Printed name of caregiver/study partner (CAPITALS)

Impartial witness: (Applicable if involvement of adult not able to read and/or write or is unable to use his extremities to sign):

Signature of impartial witness Date of Signature

Printed name of impartial witness (CAPITALS)

When completed: 1 for participant, 1 for legal representative/impartial witness (if applicable), 1 for researcher site file; 1 (original) to be kept in medical notes.

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Informed Consent Form for the Participant´s Legal Representative

Study Title: A PHASE 3, MULTICENTER, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED STUDY OF THE EFFICACY, SAFETY AND BIOMARKER EFFECTS OF ALZ-801 IN SUBJECTS WITH EARLY ALZHEIMER'S DISEASE AND APOE4/4 GENOTYPE

Protocol Number: ALZ-801-AD301 (APOLLOE4)

Sponsor: Alzheon, Inc.
Protocol Number: ALZ-801-AD301 (APOLLOE4)

Sponsor: Alzheon, Inc.

Research Site Re:Cognition Health, 45 Queen Anne Street, London, W1G 9JF

Principal Investigator: Dr. Emer MacSweeney

IRAS Project ID: 295043

Patient ID:

The participant´s legal representative should complete the following: Please initial

1. I confirm that I have read and understand the information sheet (version 2.0, dated 28Apr2021) for the above study. ☐
2. I understand that _____(study participant) currently lacks the capacity to make an informed decision about whether they can take part in this study and I understand by agreeing to act as his/her legal representative I am being asked to give permission on their behalf to join this study. ☐
3. I confirm that the pre-screening evaluation has been explained to me and I have had the opportunity to ask questions and ample time to decide whether to authorize his/her participation. I know whom to contact if I have any further questions. ☐
4. I understand that relevant sections of his/her medical records will be reviewed by representatives of the sponsor, auditors and national and foreign regulatory authorities where it is relevant to his/her taking part in the study. I give permission for these individuals to have access to those medical records. ☐
5. I consent to the processing of his/her personal data, including health data, genetic and other data for the purposes of the study as described in section "Confidentiality and Data Protection" of the information sheet. ☐
6. I agree to the transfer of his/her study related data including year of birth, age, race, ethnic origin, gender, information about his/her health and medication usage to the sponsor and to regulatory authorities both within and outside the United Kingdom. I ☐

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understand that personal data identified only by a SID number may be sent to countries that do not have the same level of data protection as the United Kingdom.

7. I agree that his/her pre-screening evaluation related data identified only by his/her SID number can be archived. ☐
8. I agree that a blood sample collected from him/her can be used for the purposes of this pre-screening APOE genotyping evaluation. ☐
9. I agree for him/her to take part in this pre-screening evaluation. ☐
10. I agree that his/her GP can be informed of his/her participation in this study ☐
11. OPTIONAL: I agree to the use of Greenphire for patient reimbursements ☐

Legal Representative

Signature of legally acceptable representative Date of Signature

Printed name of legally acceptable representative (CAPITALS)

Relationship of legally acceptable representative to participant (CAPITALS)

When completed: 1 for participant, 1 for legal representative/impartial witness (if applicable), 1 for researcher site file; 1 (original) to be kept in medical notes.

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INFORMED CONSENT FORM FOR OPTIONAL RESEARCH ON PRE-SCREENING BLOOD SAMPLES

Study Title: A PHASE 3, MULTICENTER, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED STUDY OF THE EFFICACY, SAFETY AND BIOMARKER EFFECTS OF ALZ-801 IN SUBJECTS WITH EARLY ALZHEIMER'S DISEASE AND APOE4/4 GENOTYPE

Protocol Number: ALZ-801-AD301 (APOLLOE4)
Sponsor: Alzheon, Inc.

Research Site Re:Cognition Health, 45 Queen Anne Street, London, W1G 9JF

Principal Investigator: Dr. Emer MacSweeney, 45 Queen Anne Street, W1G 9JF, 020 3355 3536

IRAS Project ID: 295043

Patient ID:

Consent to Use Blood Sample for Future Analysis with AD-Related Biomarkers		Participant to initial
I consent to the storage and use of my blood sample, until the sample is used up, for future analysis with AD-related biomarkers. I understand that this is optional.	Yes ☐ No ☐	

By signing below, I confirm I have read the section titled "BIOLOGICAL SAMPLE" and have expressed my choice. I understand I can change my mind at any time, for any reason.

Signature of participant Date of Signature

Printed name of participant (CAPITALS)

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Signature of investigator/person conducting the informed consent discussion	Date of Signature

Printed name of investigator/person conducting the informed consent discussion (CAPITALS)

Please note:

*If an adult participant can't read and/or write or is unable to use his extremities to sign, he/she only requires an impartial witness. Only participants who are **assessed** unable to give informed consent for physical or mental reasons require a Legal Representative (CTIMP).*

In support of a participant unable to consent who still is able to assent:

By crossing this box, I express my willingness to participate in this study: ☐

Investigator

(Applicable if involvement of adults partially or not able to consent themselves).

I confirm that the above participant has been assessed as:

- *partially capable to understand all aspects of this research study*

Yes ***No*** *(please circle)*

- *not capable to understand all aspects of this research study*

Yes ***No*** *(please circle)*

If partially capable, the participant might cross the above box to express his/her assent to participate, in line with the consent of his/her Legal Representative (person defined as per local regulations).

Legal Representative (Applicable if involvement of adult not able to consent themselves):

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Signature of legally accepted representative | Date of Signature

Printed name of legally accepted representative (CAPITALS)

Relationship of legally acceptable representative to participant (CAPITALS)

The caregiver/study partner signature section should be completed if the caregiver/study partner is different from the legally acceptable representative.

Signature of caregiver/study partner | Date of Signature

Printed name of caregiver/study partner (CAPITALS)

Impartial witness: (Applicable if involvement of adult not able to read and/or write or is unable to use his extremities to sign):

Signature of impartial witness | Date of Signature

Printed name of impartial witness (CAPITALS)

When completed: 1 for participant, 1 for legal representative/impartial witness (if applicable), 1 for researcher site file; 1 (original) to be kept in medical notes.