TEMPLATE DOCUMENT – NOT APPROVED FOR SITE USE

INFORMED CONSENT AND AUTHORIZATION TO PARTICIPATE IN A CLINICAL RESEARCH STUDY

TITLE OF RESEARCH: A Double-Blind, Randomized, Placebo-Controlled Study to Evaluate Efficacy and Safety of 26-Week Treatment of AR1001 in Patients with Mild to Moderate Alzheimer's Disease

Protocol No.: AR1001-ADP2-US01

Sponsor's Name: AriBio Co., Ltd.
#520, F5, Gyeonggi Business Growth Support Center,
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Republic of Korea

Principal Investigator (Study Doctor):

Main Telephone Number:
24-Hour Telephone Number:

In this consent form "you" generally refers to the patient. If you are being asked as the legally authorized representative to permit the patient to take the investigational drug, "you" in the rest of this form generally means the patient.

A. PURPOSE OF THE STUDY:

You are being asked to volunteer to participate in a research study. This form includes information about this study.

The purpose of this study is to find out if an investigational new drug called AR1001 can help people with Alzheimer's Disease and if it is safe.

AR1001 is an investigational drug. An "investigational" drug is a drug that is still being tested and is not approved for sale. AR1001 has not been approved in the United States by the U.S. Food and Drug Administration (FDA). It has been approved in South Korea for erectile dysfunction.

Alzheimer's Disease is not completely understood. Some research has shown that people with Alzheimer's Disease have vascular disease or disease in their blood vessels. It is thought that AR1001 may help the blood vessels in your brain work better.

This study will be conducted in subjects 55-80 years of age with mild to moderate Alzheimer's Disease.

B. YOUR PARTICIPATION IN THE STUDY:

This study is expected to enroll approximately 210 subjects at 15 - 25 sites in the US.

You are being invited to take part in this study because you have been diagnosed with Alzheimer's Disease. If you meet the eligibility criteria and agree to participate in the study, you may qualify to take part in the study.

In order to participate in this study, you:

- Should be between 55 and 80 years old
- Have mild to moderate Alzheimer's Disease
- Have previously had an MRI or CT scan of your brain
- Have an adult study partner who can also let your doctors know how you are doing

You should not participate in this study if you have:

- Been diagnosed with dementia that is not related to Alzheimer's Disease
- Had a stroke in the past two years
- Have uncontrolled high blood pressure
- Had cancer within the last five years (with some exceptions)
- Have kidney or liver problems
- Take any prohibited medications
- Or if your doctor thinks that it would not be safe for you to participate

This form describes the purpose, procedures, benefits, discomforts, risks, and precautions associated with this study, as well as your rights and responsibilities if you decide to participate. It also explains how your medical information will be used and who may see it.

Please take the time to read (or have someone read it to you) this consent document. Your signature on this consent form means that you agree to participate in the study as described in this consent form. Please ask the study doctor or study staff to explain any words in this consent form that you do not understand, and make sure all your questions have been answered to your satisfaction before signing this consent form. If you decide to participate, you will need to sign this consent form, your caregiver is also required to sign the form, and you will be given a copy of the signed document. The study doctor must also feel that you do not have any other medical problems or treatments that would make it unsafe for you to be in the study.

You may choose not to participate in this study. You do not need to participate in this study to receive medical care from your doctor for your Alzheimer's Disease. If you wish, you can also talk about your options with another doctor specialized in the treatment of Alzheimer's Disease, who is not part of the research team. Your doctor will not stop treating you if you decide not to take part in this study.

You may also decide to participate in this study now, but withdraw your consent later, and stop being in the study without any loss of benefits or medical care to which you are otherwise entitled.

C. DESCRIPTION OF THE STUDY; DURATION; PROCEDURES:

Summary:

Participation in this study will involve one beginning visit (Visit 1) which will be performed when your doctor determines that you can participate and you decide to participate. Visit 2 will follow about 2 weeks after the first visit. Visit 3 will be about 4 weeks after Visit 2, and Visit 4 will follow about 9 weeks after Visit 3 (about 13 weeks after you started taking the study medication). A phone call will be made 7 weeks after Visit 4 (about 20 weeks after you started taking the study medication). Visit 5 will be 6 weeks after Visit 4 (about 26 weeks after you started taking the study medication). You are also given the choice to continue on the study medication for 26 weeks more.

If you do not want to continue to take the study medication, this will be the last day you take the study medication, and the final visit (Visit 6) will occur about 2 weeks after your last dose of study medication. Your participation in the study will last for about 28 weeks from the first day you take the study medication, or until you or your study doctor decides that your participation should end.

If you do want to continue to take the study medication for another 26 weeks, you will be asked to review this form again and confirm your interest in further participation and your study doctor with confirm that you are still eligible to continue with the study medication. Visit 6 will be about 4 weeks after Visit 5, and Visit 7 will follow about 9 weeks after Visit 6 (about 13 weeks after you decided to continue taking the study medication). A phone call will be made 7 weeks after Visit 7 (about 20 weeks after you decided to continue taking the study medication). Visit 8 will be 13 weeks after Visit 7 (about 26 weeks after you decided to continue taking the study medication). The final visit (Visit 9) will occur about 2 weeks after your last dose of study medication. Your participation in the study would then last for about 54 weeks from the first day you take the study medication, or until you or your study doctor decides that your participation should end.

How long will I be in the Study?

Your participation in the main study will involve a total of 6 visits, which will take up to 30 weeks from your first visit. If you choose to participate in the extension, there will be an additional 4 visits over the next 26 weeks, and your total time of participation will be approximately 54 weeks.

The first part of the study is a screening period lasting about 14 days. During this part of the study you will have 1-2 visits depending upon how long it takes to schedule and complete the required tests. The results of these tests will help determine whether you can be in the study or not.

The second part of the study is called the treatment period. This is when you will be taking the study medication. This part is a 26-week treatment period that involves 4 visits and 1 phone call.

The third part of the study is called the extension phase. This is part of the study is optional, and you may decide at the end of your 26-week treatment period whether you want to continue taking study medication.

The last part of the study is the safety follow-up period. There is 1 visit about 14 days after you finish taking the study medication.

How will I receive my Study medication?

If you are eligible to take part in the research study and you have signed the consent form, you will be randomized (by chance) to one of three treatment groups. One of the treatment groups receive placebo, which is a tablet that looks like AR1001, but it has no active ingredient, which means that it is a dummy pill. You will have a 1 in 3 chance of being in each of these groups:

- Group A: AR1001 10 mg - 70 subjects
- Group B: AR1001 30 mg - 70 subjects
- Group C: Placebo - 70 subjects

Randomized means that you will be placed in the group by chance, like flipping a coin. Neither you, nor the study staff can choose which treatment group you will receive. This is a double-blinded research study which means that neither you, nor the study doctor will know what treatment you are receiving. In case of emergency, the study staff can find out.

In the extension phase of the study, if wish to continue and had been randomized to either Group A (AR1001 10 mg) or Group B (AR1001 30 mg), you will continue to take that dose. If you were randomized to Group C (Placebo) at the beginning of the study and you wish to continue in the study, you will be randomized to either Group A (AR1001 10 mg) or Group B (AR1001 30 mg). You will not be told at any point which Group (or groups) you have been assigned to. Either way, you are guaranteed to be assigned to the study medication during the optional extension phase.

The study drug will be provided to you by the study sponsor. Everyone in this study will take the study drug by mouth. You will be given two bottles in each kit of study drug. You will take one tablet from each bottle every day for the entire study (A total of two tablets will be taken each day). You should take the study drug in the morning before eating breakfast and store your study drug in a cool, dry place (15 – 25 °C)

You are the only one who should take your study drug. You should make sure that no one else takes it. You should take your study drug at about the same time of day on each day that you take it. You will be asked to record the date and time of each dose you take into the Dosing Diary provided.

You will need to bring your Dosing Diary, all remaining study drug, and all bottles (containers) with you to each study visit even if all the containers are empty.

What happens when I come for study visits?

Before you can start this study, the study doctor or study staff will talk to you about the study and answer any questions you or your family may have. If you decide to take part, you will have to sign this form before the study doctor or study staff can begin any study procedures. Only then can the study doctor or study staff begin the screening/wash out period.

If you decide to participate in this research study, you will be asked to come for study visits while you are in the study.

- During this first visit, your medical history will be reviewed and your height measurement will be obtained.
- During the first, third, fifth, and last visit, a 12-lead ECG will be performed
- During the first, third, fourth, fifth, and last visits, a blood sample and a urine specimen, will be taken, and if you are a female and able to have children, a urine pregnancy test

will be performed. If you decide to participate in the extension study, these will be repeated at the sixth, seventh, and eighth visits as well.

- The amount of blood taken overall in this study will be about two tablespoons per visit (or about ten tablespoons (about 150mL) in total). For comparison, a standard blood donation is approximately 500 mL (2 cups). If you participate in the extension part of the study, the amount of blood that will be taken over all of the visits (over approximately 54 weeks) will be about twenty tablespoons (about 300ml) in total.
- During visits, a complete physical examination will be performed including your pulse, blood pressure, respirations, and weight.
- During the first visit and other visits, you will be asked to complete surveys which will assess your memory and your general health.
- During visits, you will be asked about any medications you are taking (or have taken) as well as your overall health.
- During visits, a blood draw will be conducted to collect a plasma sample for future testing (to help understand Alzheimer's Disease).

Clinic visits should last approximately 90 minutes. Additional time may be necessary to complete the ECG during a single visit.

Between scheduled clinic visits, your doctor will be contacting you to see if you are okay and if you have experienced any changes to your overall health.

Approximately 14 days after your last treatment with study drug, you will be asked to come back to the clinic for your last study visit or "follow-up visit". You will be given a complete medical examination including your pulse, blood pressure, respirations, height, and weight. You will be asked about any medications you are taking (or have taken) as well as your overall health.

In case of early withdrawal from the study, you will be asked to complete one regular visit and to come back to the clinic 14 days later for a follow-up visit.

What are my responsibilities if I choose to be in the Study?

While you are in the study, you must:

- Follow the instructions you are given.
- Come to the study center for all visits with the study doctor.
- Take your medication as directed and bring it with you to all your scheduled office visits.
- Keep your diaries updated, as instructed, and bring them to each visit.
- Complete your questionnaires as instructed.
- Tell the study doctor or study staff about any changes in your health.
- Tell the study doctor or study staff if you want to stop being in the study at any time.
- Respond to the study doctor when they contact you by telephone to see if you are doing OK.
- Contact your study physician between visits for any adverse symptoms.
- A subject should inform his/her other treating physician about study participation.

You must not:

- Have participated in other drug studies within 30 days of study start or for the duration of the study.

Below you will find an extensive list of medications that you are not allowed to take if you take part in this research. You may not recognize any of them. If you are taking medication, it is important for you to tell the study staff what you are taking or to show them the bottle and/or packaging in order for the study staff to check if it is safe for you to participate in this research. Please also consult your primary care physician or neurologist if you want another opinion on whether you should take part in this research.

Routine use of the following medications (by generic name) during this trial is not allowed:

Alpha 1 Blockers: (usually used to treat high blood pressure and enlarged prostate)

- alfuzosin
- doxazosin
- prazosin
- silodosin
- tamsulosin
- terazosin

PDE-5 inhibitors: (usually used to treat erectile dysfunction and pulmonary hypertension)

- avanafil
- sildenafil
- tadalafil
- vardenafil

Nitrate medications: (usually used to prevent or treat chest pain (angina) and heart conditions such as coronary artery disease). These may be prescribed to you as sublingual tablets, aerosols, pump sprays, ointments, infusions, patches, or capsules.

CYP3A4 inhibitors/inducers: (These are drugs that can increase or weaken certain drug reactions making them more or less effective)

amiodarone	ethinyl estradiol	miconazole	progesterone
cannabinoids	ethosuximide	nafcillin	quinidine
carbamazepine	fluconazole	nefazodone	quinine
clarithromycin	fluvoxamine	nelfinavir	quinupristine and dalfopristin
clotrimazole	gestodene	nevirapine	rifabutin
cyclosporine	glucocorticoids	norfloxacin	rifampin
danazol	grapefruit juice	norfluoxetine	ritonavir
delavirdine	griseofulvin	oxcarbazepine	saquinavir
dexamethasone	indinavir	oxiconazole	St John's wort
diethyldithiocarbamate	isoniazid	phenobarbital	troglitazone
diltiazem	ketoconazole	phenylbutazone	troglitazone
erythromycin	mibefradil	phenytoin	troleandomycin
		primidone	

*Please ask your doctor if you have any questions about medications that you are currently taking.

TESTS AND PROCEDURES:

Apart from some questionnaires, and pregnancy testing for female patients, all of the required tests and procedures for this study are the same as those commonly used by doctors who care for patients with Alzheimer's Disease. None of the tests or procedures in this study are investigational.

1. **Health and Medication Questions:** You will be asked about your medical history. You will be asked what medications you have taken in the last 30 days. You will also be asked what medications you are taking while you are in the study. You may also be asked to provide consent for release of your medical records from previous doctors to your current doctor.

2. **Physical Examination:** At each visit, a complete physical examination includes examination of your general appearance, skin, neck (including thyroid), eyes, ears, nose, and throat, abdomen, hands, feet, lymph nodes, lungs, and heart.

3. **Vital Signs (Blood Pressure, Pulse, and Breathing), Height, and Weight):** At each visit, study staff will check your blood pressure by putting a band around your arm. This will squeeze your arm for about a minute. The measurements will be taken with you sitting or lying down after having rested for a 5-minute period. The same position should be used at all visits. Study staff will check your pulse and breathing rate, and take your weight. They will also measure how tall you are at your first and last visit.

4. **ECG:** An electrocardiogram (ECG) measures the electrical activity of your heart. You will be asked to rest, lie down, and remain in a lying position during this exam. Small pads will be attached to your chest, arms, and legs. These pads are connected to a recording machine using wires. Most people do not experience discomfort during the procedure. An ECG will be done at Visit 1 (Screening), Visit 3 (about 4 weeks after you start the study drug), and Visit 5 (about 26 weeks after you start taking the study drug). If you participate in the extension, you will also have an ECG at Visit 6 (about 30 weeks after you started study medication) and Visit 8 (about 52 weeks after you started study medication).

5. **Blood Tests:** During this study, samples of blood for blood tests will be drawn by putting a needle into a vein and taking out blood. The blood tests performed include:
   - Routine lab tests: blood cell counts, measurement of salts, minerals, sugar, enzymes, and proteins to measure your general health (every visit)
   - The amount of blood to be collected at each visit will be slightly different, but the most blood collected at any one visit is about 10 milliliters (about 2 teaspoons).

6. **Urine Tests (urinalysis):** You will also be asked to provide a urine sample during your visit. The tests performed on your urine samples include:
   - Routine urine lab tests to measure your general health (every visit)
   - Pregnancy test (every visit): If you are a woman who can become pregnant, it is important that you contact the study doctor if at any time you believe that you may be pregnant. If you become pregnant, you must stop taking the drug immediately.

7. **Cognitive Testing:** You will be asked to fill out 7 different surveys that ask about your memory and how you are feeling mentally. They will include asking you to remember things and questions about your activities, and any trouble you might be experiencing. You will

answer all these questions 3-4 times during the study, and there would be an additional 2-3 times that you will be asked to complete these surveys, if you participate in the extension.

8. **MRI or CT Scan**: Upon approval of the study sponsor, the MRI or CT scanner may be used if you have not had a scan since you first saw a doctor for Alzheimer's disease. The MRI or CT will be used to collect detailed pictures of your brain while you are lying still on the scanner bed. You are asked to fast (not eat) for 12 hours prior to this procedure. Monitors will be comfortably secured to you to measure your pulse and respiration rates during the scan. During the scans it is essential for you to remain as still as possible to avoid any blurring of the images. Your head may be held in place by foam padding to help you keep still during the scan. The procedure takes approximately 1 hour. We will situate you as comfortably as possible and then run several scans that may take 2-10 minutes each. In between scans, you will be able to communicate to the scan operator through an intercom.

If you agree, samples of blood collected throughout the study will be used and stored for up to 25 years for future research and to help learn more about Alzheimer's Disease. Your name and any other identifying information will not be kept with your samples.
The stored samples may be used to create new products, tests or discoveries that could be patented, licensed or otherwise used by AriBio for commercial gain. There are no plans to provide financial compensation to you should this occur. You can be in the study even if you do not agree to the storage of your samples for future research.

D. PAYMENTS/COST:

Will I be paid for participating in the Study?

You will be paid $*XXX* for participating in this study.

You may be able to have any reasonable travel expenses that you or your partner or caregiver personally incur as a result of being in this study paid back to you.

Examples of costs that might be paid back to you include modest, overnight accommodations, mileage reimbursement, cost of transport (e.g., flights, train, taxi fares) and/or meals required during long travel periods or overnight stays. You will need to submit any related receipts and/or follow other instructions of the study center in order to be reimbursed for such expenses These travel expenses will need to be pre-approved by the sponsor.

Will I have to pay any costs for participating in the Study?

The study medication and study related tests, procedures and visits required by the study are provided at no cost to you. The costs of standard medical care that are not part of the study will be billed to you and/or your insurance company in the usual way.
There will be no additional cost to you for taking part in this study except for costs you may have when traveling to and from the study site or taking time off from work.

AriBio is paying the study doctor to perform this study.

E. POTENTIAL RISKS AND DISCOMFORTS:

This section describes some of the risks and discomforts that you may experience during your participation in this study. It is possible that the particular treatment or procedure may involve risks to you that are not currently known or foreseeable. As with any investigational new drug or research study procedure, there are risks that are not known that may be serious and may

even cause death.

You may have side effects while on this study. We will watch everyone in the study for any side effects.

Side effects may be mild or serious. We may give you medicines to help lessen side effects. Some side effects will go away as soon as you stop taking the drug. In some cases, side effects can be serious, lasting or may never go away.

AR1001 has been given to approximately 342 men with erectile dysfunction in clinical trials at doses up to 400 mg daily. Most side effects have been mild to moderate. The most common side effects were mild headaches & flushing.

Other side effects due to this type of drug (PDE5 inhibitor) that are possible are:

- Back pain and muscle aches
- Erection or priapism (a prolonged and unwanted erection of the penis that occurs without sexual stimulation) in males
- A change in your vision in either one or both eyes
- A change in your hearing
- Dizziness or low blood pressure
- Heartburn
- Nasal congestion
- Nausea
- Rash

If you have any of these, you should tell your study doctor about them.
There may be other side effects that may happen and are not known now. The study drug can cause an allergic reaction in some patients. Certain problems can be dangerous if not treated quickly; call your doctor right away if you:

- Feel very tired or faint
- Feel pain or sick in your stomach and not want to eat
- Develop a rash of any kind

Call your study doctor right away if you have any of these side effects.

Pregnancy: The risks to any baby that may be conceived by you or your partner while you are taking this drug are unknown. Therefore, women in this study who can become pregnant (that is, ovulating, pre-menopausal, not surgically sterile) or are nursing and all men in this study will be required to be sexually abstinent (not have sex) or use a medically accepted contraceptive (birth control) regimen throughout this study and for 30 days after the last study visit, as outlined below.
Acceptable methods for male participants at time of 1st dose of AR1001 and until 30 days after study completion are:

- Practice abstinence (not have sex at all)
- Use condoms and occlusive cap (diaphragm or cervical/vault caps) with spermicide throughout the study
- Be surgically sterile before the baseline visit (e.g. vasectomy)

Acceptable methods for female participants at time of 1st dose of AR1001 and until 30 days after study completion are:

- Practice abstinence (not have sex)
- Be surgically sterile before the Baseline visit
- Use hormonal contraception (oral, implant, injection, ring, or patch) for at least 3 months before the Screening Visit and throughout this study
- Have an intrauterine device (IUD) that meets the <1% failure rate stated in the product label, in place before the Baseline Visit and throughout this study
- Double-Barrier Method: condom and occlusive cap (such as a diaphragm) in combination with spermicide

Please ask the study doctor if you have any questions about the acceptable methods of birth control that must be used while participating in this research study. If you or your partner becomes pregnant during this study, please notify the study doctor immediately.

Blood samples: You will be asked to provide blood samples as part of the study procedures at every visit. The amount of blood taken is considered safe. When blood samples are taken, a needle is put into a vein in your arm. You might get a bruise where the needle went in. Occasionally, someone becomes dizzy or faint when blood is drawn and there is a rare chance of infection.

F. POTENTIAL BENEFITS:

This research is not designed to diagnose or treat your Alzheimer's Disease. There may be no benefit to you by participating in this study. This study includes procedures that may change the treatment you would otherwise receive. The knowledge gained from this research study may be of benefit to you and others with Alzheimer's Disease in the future.

G. ALTERNATIVES TO PARTICIPATING IN THE STUDY:

You do not have to participate in this study to receive ongoing care for your condition. If you decide not to be in this study, your doctor will still monitor and treat your Alzheimer's Disease as usual. Current approved drugs for Alzheimer's Disease include: Acetylcholinesterase inhibitors (tacrine, donepezil, rivastigmine, galantamine) and an N-methyl-D-aspartate (NMDA) receptor antagonist (memantine). If you are taking any of these medications, you will need to have been on them for at least 3 months in order to take part in this research. Your doctor will also talk to you about other things you can do for Alzheimer's Disease.

H. CLINICALTRIALS.GOV:

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

I. CONFIDENTIALITY:

Your private information and your medical record will be shared with individuals and organizations that conduct or watch over this research, including:

- The research sponsor
- People who work with the research sponsor
- Government agencies, such as the Food and Drug Administration
- Aspire Independent Review Board (IRB) that reviewed this research

We may publish the results of this research. However, we will keep your name and other identifying information confidential.

We protect your information from disclosure to others to the extent required by law. We cannot promise complete secrecy.

Data or specimens collected in this research might be deidentified and used for future research or distributed to another investigator for future research without your consent.

J. COMPENSATION/TREATMENT IN THE EVENT OF INJURY:

There may be risks associated with this study that are not known. Despite all precautions, you might develop medical complications from being in this study.

If you sustain any injury during the course of the research or experience any side effect to a study drug or procedure, please contact the study doctor at the phone number listed on page 1 of this document. If you do have such an injury or side effect, the study doctor will help you get medical treatment. You do not give up any rights to seek payment for personal injury by signing this form.

If you experience a medical emergency, call 911 or contact any doctor or emergency room. Let them know you are in a clinical study and the name of your study doctor.

AriBio has agreed to pay the actual and reasonable medical expenses for the treatment of injuries that are caused directly to you by you taking the study drug as you are supposed to, or from procedures that you are doing only because you are in the study. These medical expenses will be paid so long as they are not already covered by your insurance company, national health care provider or any other type of insurance that you may have for medical expenses. The study doctor must authorize such treatment, unless you need urgent treatment in which case you must advise your study doctor as soon as possible of the treatment provided to treat your injury. AriBio must have confirmation that the study doctor has followed the study plan. You should ask your insurance company or study doctor any questions that you might have about potential coverage for research-related injuries.

Additional compensation (such as for lost wages and/or pain and suffering) as a result of a study-related injury is not available. No other compensation has been set aside by AriBio.

K. VOLUNTARY PARTICIPATION:

Your decision whether to be in this study or not be in the study is completely voluntary (of your free will). If you decide not to take part in this study it will not affect the care you receive and will not result in any loss of benefits to which you are otherwise entitled.

You will be told of any significant new findings developed during the course of the research that may affect your willingness to continue in the research.

L. WITHDRAWAL FROM THE STUDY:

If you decide to take part in the study and later change your mind you may withdraw your consent and discontinue your participation at any time. Your decision will not affect your ability to receive medical care for your disease and you will not lose any benefits to which you would otherwise

be entitled. If you do decide to withdraw your consent, please contact the study doctor at the contact information listed on page 1 of this document and let know that you are withdrawing from the study.

The study doctor or another member of the study team will discuss with you the things you should know about leaving the study. You will be told how to withdraw from the study. You will also be asked to return any unused study medication and to return for a final check-up.
The study doctor may also decide to withdraw you from the study for other reasons. Some possible reasons for withdrawing you from the study would be worsening of your health, a serious adverse reaction to the study drug or a study specific procedure, or other conditions that might make it harmful for you to continue in the study. You might also be withdrawn by the doctor if you need treatment that is not allowed in the study, if you don't keep your appointments, follow directions, or take medications as instructed. You may also be withdrawn if AriBio cancels the study for any reason or an independent data safety monitoring committee recommends your withdrawal for safety reasons.

M. CONTACT PERSON(S):

If you have questions, concerns, or complaints, or think this research has hurt you or made you sick, talk to the research team at the phone number listed above on the first page.

This research is being overseen by Aspire Independent Review Board ("IRB"). An IRB is a group of people who perform independent review of research studies. You may talk to them at 1-877-366-5414 (toll-free), email@aspire-irb.com if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.

N. OPTIONAL STORAGE OF SAMPLES AND FUTURE RESEARCH:

Human Biological Samples for Future Research:

Research using human biological samples is an important way to try to understand human disease. You have been given this information because the study doctor wants to save your biological samples taken as part of this study (as described in Section C) for future research. There are several things you should know before allowing your biological to be studied.

Because your samples will not be linked to your name after they are stored, you cannot withdraw your consent to the use of the samples after they are taken.

The results of the study of your samples will be used for research purposes only and you will not be told the results of the tests.

_____ Yes, I consent to my samples being saved for future research

_____ No, I do not consent to my samples being saved for future research

O. EXTENSION PHASE CONSENT:

Participation in the Extension Phase:

After completing the first 26 weeks of study treatment, you are being given the option to continue on this study for another 26 weeks. You will be randomized to the same dose that you have been taking if you were on active drug. If you were previously assigned to the placebo group, you will be randomized to either Group A (AR1001 10 mg) or Group B (AR1001 30 mg). You will not be told which group you have been assigned to,

Please mark one of the two lines below.

_____ **Yes, I consent to participate in the Extension Phase.**

_____ **No, I do not consent to participate in the Extension Phase.**

AUTHORIZATION AND CONSENT:

By signing this form, I am confirming that I have read (or someone has read to me) and understand the information above. I voluntarily give my consent to participate. I will be given a complete copy of this signed and dated form to keep. After I finish the study, I understand the study doctor or a staff member may need to contact me (or my legal representative) for safety related follow-up or to provide me with new information resulting from the study.

By signing this form, I am not giving up any of my legal rights and I give permission to the researchers to use [and give out] information about me for the purposes described in this form. By refusing to give permission, I understand that I will not be able to be in this study.

COMPLETE APPROPRIATE ITEM(S) BELOW:

Patient Authorization and Consent

Signature of adult subject capable of consent or adult subject's legally authorized representative	Date
Printed Name of Adult Subject	

** If the adult subject listed above is unable to legally consent, please provide them with the assent document and have the subject's legally authorized representative sign above.*

Caregiver (required)

As a caregiver, you may be required to assist in the completion of the questionnaires, diaries, or other aspects of the study.

I confirm I witnessed the process of authorization and consent. The patient (or legal representative named above) read this form or had this form read to them, was given the chance to ask questions, appeared to understand and accept the answers, and signed or made his/her mark above as agreement to enroll in the study and permit the researchers to use [and give out] health information.

Signature of Caregiver	Date
Printed Name	Relationship to the Patient

Person Administering Authorization and Consent

I confirm that the participant was given an opportunity to ask questions about the study, and all questions asked by the participant, or their legal representative, have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent or authorization, and the consent and authorization has been given freely and voluntarily.

A copy of this signed Informed Consent and Authorization form will be provided to the participant.

Signature of Person Administering Consent	Date
Printed Name	

**All subjects unable to consent are required to assent, unless the investigator determines that the capability of the subject is so limited that the subject cannot reasonably be consulted.*

AUTHORIZATION TO USE AND DISCLOSE OUR PERSONAL HEALTH INFORMATION:

Private information that identifies you may be used or shared for the purposes of this study. This section describes how your personal information (such as your medical records, current and past health information, and health information from tests and procedures you have done while in this study) will be used and shared in this study, and the ways in which the study doctor and the study team will safeguard your privacy and confidentiality.

If you agree to be in this study, the study doctor and the study team will ask you to have the tests and procedures described in Section C. Some of these tests and procedures may have been done as part of your regular care. The study doctor and the study team will use the results of the tests and procedures to treat you and to complete this study. The results of these tests and procedures will be kept in your medical records and will be reported to the study sponsor, AriBio, or one or more of their designated representatives. Results of tests and procedures done just for this study and not as part of your regular care may not be included in your medical record.

Other persons and organizations, regulatory agencies such as the U.S. FDA and agencies in other countries, study monitors, the IRB(s) overseeing the research, and other AriBio representatives may review your information during the course of this study to carry out their duties under this study. Except as noted above or when required by law, study information that identifies you by name, social security number, address, telephone number, or any other direct personal identifier will not be shared with persons and organizations outside of the study doctor and his/her study team.

When your study information is shared outside of the study doctor and the study team as part of the research, the information that can identify you – the information listed above – will be removed and your records will be given a unique code number. the study doctor and the study team will not reveal the code key, except as required by law. If information about this study is to be published or presented, any information that identifies you personally will be removed.

If you choose to, you may use transportation or accommodation assistance provided by a third-party travel organization which has been designated by AriBio for this study.
If you use the designated third-party travel organization, personal identifier information as required by International Transportation Security Administration

rules and regulations, or as needed to secure hotel accommodations, will be required to be shared outside of the study site. The designated third party travel organization will not share your personal identifier information with AriBio or any other organization except as required by law.

The study doctor and the study team will try to keep your information confidential, but absolute confidentiality cannot be guaranteed. After its release, information that can identify you may no longer be protected under law. Once your health information is released, it may be redisclosed by the recipient.

Suspension of Your Right to Access Protected Health Information:
You have a right to inspect and obtain a copy of your personal health information, including personal health information maintained in the study records. The right to inspect and obtain your personal health information in the study records will be suspended during the study to protect the integrity of the study results, but you can have access to your study records after the research is completed.

Voluntary Participation:
Your authorization to collect and use your information for the purpose of this study is voluntary. However, if you do not provide your written authorization for the use and disclosure of your information, you cannot participate in this study. Refusing to sign this form will not affect your health care (or payment for your health care) outside of this study.
If you decide to stop participating in the study, you may also revoke your authorization for researchers to collect, use, and disclose any additional personal health information that could identify you. To revoke your authorization, you must tell the study doctor in writing. If you revoke your authorization, no new personal health information that can identify you will be gathered from you or your existing medical records. However, information that is in your study records at the time that your authorization is ended cannot be removed and may be used to complete analysis and reports for this study.

Retention of Your Study Information:
The study information relevant to you will be kept in your specific study records and/or your hospital medical records until AriBio or study doctor determine they are no longer required to keep these records for inspection by a regulatory agency such as the FDA.
At that time, one of two things will happen: the study specific information that is not in your medical records will be destroyed, or information that identifies you will be removed from the study records held by the study doctor or institution. Any information relating to your participation in this study that is in your medical

records may be kept indefinitely depending on the requirements of the institution responsible for your records.

Authorization:

If you decide to participate in the study, you must sign and date this authorization and consent form. The authorization to use and disclose your information will expire on December 31, 2050.

You will receive a copy of this form.

Patient Authorization and Consent

Signature of adult subject capable of consent or adult subject's legally authorized representative	Date
Printed Name of Adult Subject	

** If the adult subject listed above is unable to legally consent, please provide them with the assent document and have the subject's legally authorized representative sign above.*

Caregiver (required)

I confirm I witnessed the process of authorization and consent. The patient (or legal representative named above) read this form or had this form read to them, was given the chance to ask questions, appeared to understand and accept the answers, and signed or made his/her mark above as agreement to enroll in the study and permit the researchers to use [and give out] health information.

Signature of Caregiver	Date
Printed Name	Relationship to the Patient