To be Printed on Hospital/Institute Headed Paper

Participant Information Sheet and Informed Consent Form

Study Title:	An adaptive, Phase 2, double-blind, randomized, placebo-controlled, multicenter study to evaluate the safety, tolerability, immunogenicity, and pharmacodynamic effects of ACI-7104.056 in patients with early stages of Parkinson's disease
Protocol Number:	ACI-7104-PD-2103
EU CT Number:	2022-500292-31-00
IRAS ID:	1006102
Sponsor:	AC Immune SA EPFL Innovation Park - Building G CH-1015 Lausanne, Switzerland
Principal Investigator /Study Doctor:	<Print name of Principal Investigator>
Site Number:	<Site Number>
Site Name and Address / Study Centre:	<Site Name and Address>
Site Phone Number:	<Insert Site Telephone Number>

1.0 Introduction

In this Participant Information Sheet and Informed Consent Form (PIS-ICF), "you" refers to the person taking part in the study.

AC Immune SA (the Sponsor) is running a research study to see if a test medicine, the study vaccine, not yet approved for market, named ACI-7104.056, will help in the treatment of early stages of Parkinson's disease and how safe it is to use in people.

You are being invited to take part in this research study because you have been diagnosed with Parkinson's disease and are currently in the early stage of it.

This PIS-ICF is provided to allow you to make an informed decision on whether you would like to take part in the study. Take as much time as you need and discuss this information with who you wish to help you decide. You are free to ask questions to your study doctor at any time. Your participation is voluntary, if you do not want to take part you do not need to do anything, and your study doctor will discuss what other treatments may be available to you. If you do decide to take part, you will be required to sign this PIS-ICF before you can participate in the study, however you can still withdraw your consent at any time. You will receive a copy of the signed PIS-ICF for your records.

2.0 What is the purpose of this study and who can join?

The purpose of this research study is to assess the safety and tolerability of the study vaccine (ACI-7104.056) and the antibody response induced by the study vaccine in people with early Parkinson's disease who are between 40 and 75 years old. This treatment is called "vaccination" whereby a vaccine is received to produce immunity against a disease. The vaccine in this study has been designed to facilitate the production of antibodies. Antibodies are proteins that the body uses to fight substances which recognised as alien, such as bacteria, viruses, and foreign substances in the blood. The antibodies

induced with the study vaccine selectively recognise alien protein aggregates, called alpha-synuclein aggregates. Alpha-synuclein aggregates are thought to contribute to the progression of Parkinson's Disease and are known to accumulate in people with Parkinson's disease (PwP). Therefore, reduction of alpha-synuclein protein levels is a promising strategy to control the formation of alpha-synuclein aggregates in the hope that this may slow the rate of progression of Parkinson's disease.

Your study doctor will explain when, how often and how the study vaccine will be administered.

The study will have up to 3 cohort groups of 16 participants in each cohort. Each participant will receive either the study vaccine or placebo. You may receive a placebo which looks like the study vaccine but contains no medicine and is not expected to have any effect. You will have a 3:1 chance of receiving the study vaccine or placebo randomly, both vaccine and placebo, are referred to as 'study medicine' for the rest of this information sheet This allows the Sponsor to explore whether the study vaccine works as well as, or better than the placebo.

One of the initial potential 3 cohorts may be expanded in order to reach an overall total of up to 150 participants in the study.

In this study neither you nor your study doctor will know which study medicine you are receiving.

3.0 What will happen in the study and what are the risks?

Your participation in the study will last approximately 108 weeks (approx. 2 years), comprising of a screening period of up to 8 weeks (approx. 2 months), a 74-week (approx. 18 months) double-blind treatment period, and a 26-week (approx. 6 months) post-treatment follow-up period to evaluate the safety, tolerability, and immunogenicity (the ability of cells/tissues to provoke an immune response) of the study vaccine.

The screening period can be up to 8 weeks (approx. 2 months) and will start from the signature of this PIS-ICF form to randomisation to a study treatment arm. Screening assessments may be performed at sequential visits over multiple days, where your study doctor will check to see if you are suitable to take part in the study. This will involve completing some procedures and tests. If you are suitable to take part in the study, you will be randomly allocated to a study treatment (called randomisation).

After randomisation, you will have at least 14 visits to your study doctor, every 2 weeks for the first 6 weeks, at week 12, 14, 24, 26, 48, 50 and 74 during the treatment period, and at week 76, 87 and 100 during the follow up period. Home or remote visits may be allowed in some situations, if you are in agreement and where permitted by local regulations, except for assessments that cannot be performed at home. For more details regarding the approximate duration of each study visit please refer to table 1.You will receive treatment for 74 weeks, at the end of treatment the study doctor will continue to monitor you for 26 weeks.

During your participation in the study you will be asked to come back for further visits and you will have some further procedures and tests (including collecting blood, urine and cerebrospinal fluid samples as well as brain scans). In total 700 ml of blood and 36 ml of cerebrospinal fluid will be collected during the study. During the study your blood and urine samples will be stored at and tested by ICON Central Laboratory (Europe) in Ireland. After completion of the study your samples will be stored at a bio storage facility for up to 10 years.

If you are a woman capable of having children, you will be required to have a pregnancy test to make sure you are not pregnant.

Information about what tests will be done and when they will be done are shown in the table 1 below.

Table 1: Schedule of Assessments

Procedure		Treatment Period											Follow up			Duration
	Screening	week 0	Week 2	Week 4	Week 6	Week 12	Week 14	Week 24	Week 26	Week 48	Week 50	Week 74	Week 76	Week 87	Week 100	Minutes
Medical history	X															30
Inclusion/Exclusion criteria	X															60
Physical & Neurological Examination	X	X		X		X		X		X		X				30
Temperature, heart rate, blood pressure, breathing rate	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	15
Cognitive/Clinical Assessment	X	X				X		X		X		X			X	210
Lumbar Puncture	X							X					X			60
Blood samples	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	60
Urine samples	X	X		X		X		X		X		X		X	X	15
Pregnancy test		X		X		X		X		X		X			X	10
Electrocardiogram (ECG) – to measures your heart rhythm and activity	X	X***		X***		X***		X***		X***		X***			X	15
MRI- Magnetic Radiographic Imaging	X							X		X		X			X	45-90
DaT-SPECT Imaging	X									X					X	30
Treatment (Vaccination)		X		X		X		X		X		X				15
Duration of visit* (Approximate)	10 hours	6 hours**	1 hour	2.5 hours	1 hour	2.5 hours	1 hour	8.5 hours	1 hour	8 hours	1 hour	7.5 hours	2 hours	1.5 hours	7 hours	

*long study visits may be split over several days if you wish

the first 3 participants will be required to stay at the hospital over a 24 hour period* ECG to be performed after treatment administration

For further explanations of procedures and associated risks please refer to table 2.

During the screening period, your study doctor will assess if you are able to participate in the study.

- At your first visit, you will receive information about the study, and you will have the opportunity to ask questions. If you agree to take part in this study, you will be asked to sign this PIS-ICF before any study procedures can take place. After you have signed the PIS-ICF, you will be asked questions and examinations will be done by the study team to make sure you do not have any health issues that would put you at risk during the study. If you are suitable to take part in the study, you will be asked to come back to the site for 11 visits during the study treatment period and you will receive 6 injections of the study medicine (either the active vaccine or a placebo) - at Week 0 (start of treatment); Week 4; Week 12; Week 24; Week 48; and Week 74.
- During the treatment and follow up periods, you will be asked to report any adverse effects you may be experiencing or have experienced as well as changes to your medication since the last visit. Your study doctor will also assess the global tolerability of study vaccine during the treatment and follow up periods of the study.

All assessments/ procedures are explained in the table below.

Table 2: Overview of procedures and risks associated with trial related assessments

Assessment	Explanation	Risks
Medical History	Review of medical history (personal information (i.e. name, year of birth, gender, race, etc.), information about the year of onset of Parkinson's disease, your family history and previous medications for Parkinson's disease, information regarding your general medical/procedure history and current and prior medications for other diseases, and questions about symptoms that you may be having.	Personal data will be collected and recorded for the purposes of the study during this assessment. Information on how your personal date will be protected is detailed in Section 13 below.
Physical Examination	Assessment of general appearance, the head, eyes, ears, nose, throat, heart, chest, lungs, abdomen, lymph nodes, extremities (arms and legs), peripheral pulses (wrist and ankle), skin, and any other physical conditions of note.	There is no perceived risk to you during this assessment.
Neurological Examination	Examination of the nervous system: examination of the cranial nerves (nerves in the head and face), upper and lower extremities (arms and legs) for muscle strength, reflexes, sensation, and cerebellar function (this part of the brain controls balance for walking and standing, and other complex motor functions).	There is no perceived risk to you during this assessment.
Cognitive/Clinical Assessment	An assessment of your cognitive status and an interview with you on how you function in daily life, using paper based questionnaires (assessment of your memory, general functional ability, thoughts, feelings, or suicidal ideation).	Personal and sensitive data will be collected and recorded for the purposes of the study during this assessment. Information on how your personal date will be protected is detailed in Section 13 below.
Temperature, heart rate, blood	A measurement of your vital signs (signs checked to evaluate your health condition	There is no perceived risk to you during this assessment.

pressure, breathing rate	such as blood pressure, pulse and breathing rate, temperature).	
Electrocardiogram (ECG) – to measures your heart rhythm and activity	ECG - assessment of your heart function	The sticky pads placed on your chest may cause skin irritation.
MRI- Magnetic Resonance Imaging	A technique which uses a magnetic field to produce an image of your brain which will be examined for evidence of inflammation of the brain and other brain diseases.	If you do not like confined spaces it may make you feel uncomfortable being in the MRI scanner. You may also feel uncomfortable due to the noise produced by the machine. You will need to stay still during this procedure for up to an hour or more.
Lumbar Puncture (also called spinal tap)	This procedure involves insertion of a needle into the spinal canal to collect the cerebrospinal fluid for testing. The cerebrospinal fluid is the liquid that is in the ventricles in the brain and surrounds the spinal cord within the skull and backbone. In most cases, the patient is asked to sit and bend forward or lay down on an examination table, and the spinal needle is inserted after a numbing agent is applied to the skin at the lower back. This procedure should last approximately 1 hour as you will be required to lay flat after the procedure for a period of time.	Post-lumbar puncture headache (1 of 4 participants experience headache after the lumbar puncture). Back discomfort or pain. The pain might radiate down the back of your legs. Bleeding: Bleeding may occur near the puncture site or, rarely, in the epidural space surrounding the spinal cord.
Blood Sample Collection	Routine haematology, biochemistry, antibody titers, peripheral blood mononuclear cell (PBMC), ribonucleic acid (RNA), HIV, Hepatitis B and C, Syphilis, Vitamin B12, Serum Folate, thyroid function (if you are a female able to have children, the blood sample collected will be also used to confirm that you are not pregnant).	Discomfort due to swelling or bruising around the injection site Light-headedness and fainting (uncommon) Small risk of infection at the injection site
Urine Test	For routine urine evaluation	There is no perceived risk to you during this assessment.
Urine pregnancy test	A dipstick will be placed in the sample of urine that will confirm if there is a presence of pregnancy hormone.	There is no perceived risk to you during this assessment.
DaT-SPECT imaging	A technique to produce an image of your brain which can help improve the accuracy of Parkinson's disease diagnosis. DaTSCAN™ (ioflupane) is an authorised radiotracer used to perform the imaging of	The test involves having an injection of radioactive tracer into a vein in your hand or arm. The radiation can sometimes take as long as a few days to pass out of your body. The amount of radiation you receive from these

	dopamine transporter, a molecule found on dopamine neurons in the brain.	scans is similar to what you receive from natural background radiation every two years. If you take part in this study, you will have three DATScans. These will normally be extra to those that you would have if you did not take part. These procedures use ionising radiation to form images of your brain and provide the study doctors with essential information about the effectiveness of the study drug. Ionising radiation may cause cancer many years or decades after the exposure. We are all at risk of developing cancer during our lifetime. 50% of the population is likely to develop one of the many forms of cancer at some stage during our lifetime. Undergoing three DATScans in this study may increase the chances of this happening to you to about 50.07%, an increase of 0.07%.. In less than one percent of people reported having side effects: headache, nausea, upset stomach, sensation of motion, dry mouth, and dizziness.
Vaccination	The study medicine will be administered as an intramuscular injection (usually in the muscle of your upper arm).	Site reactions such as Erythema (redness), swelling and induration (a deep thickening of the skin), mostly of mild or moderate severity and rarely of severe intensity.
Receiving live vaccinations	The use of other live vaccines are prohibited during participation in the study. Live vaccines are any vaccine that uses a weakened form of a virus that causes a disease	If you are required to receive a live vaccine at any time during participation in this study please discuss this with your study doctor as soon as possible.

- If you are one of the first three participants randomised in the study, you will be kept under clinical observation at the hospital for at least 24 hours after the first administration of study vaccine or placebo and monitored regularly at 1, 2, 4, 8, 12 and 24 hours. During that 24-hour period, vital signs will be monitored and the injection site will be observed on a regular basis. A physical examination will be performed before you are discharged. Your study team will inform you whether or not you are one of the first three enrolled participants.

For all subsequent participants (apart from the first three participants enrolled) you will be asked to stay at the hospital for at least 4 hours after each injection to observe for any initial reactions to the study medicine.

Unscheduled visit:

Your study doctor may schedule supplemental visits to verify whether it is safe for you to continue participation in the study. During these visits you will be asked to provide information regarding your current medications and any symptoms and side effects that you may be having since your last visit. A physical and neurological examination will be completed, including your vital signs and you may also be required to have a blood test for safety evaluation. Other assessments may be also considered by your study doctor.

Premature Termination:

If you discontinue the study early, you will be encouraged to complete a safety assessment evaluation visit. During this visit you will be asked to provide information regarding your current medications and any symptoms and side-effects that you may be having since your last visit. A physical and neurological examination will be completed, including your vital signs and you may be asked to have a blood test for safety evaluation. Other assessments may be also considered by your study doctor.

Exploratory Research

Exploratory research means that your data collected or samples taken during the study will be stored by the Sponsor and may be analysed for further research purposes.

This research may help scientists to better understand:

- How Parkinson's disease and its symptoms work
- The effect of the study vaccine and/or other medications on the body
- How the study vaccine is processed by the body
- Who could benefit from the study vaccine
- Why some people have adverse events

No analysis will be performed on your samples or data without prior approval from a Research Ethics Committee.

Brain advanced MRI scans will be used to explore the effect of the study vaccine on the brain in participants at the hospitals where advanced MRI resolution pictures are possible. In this subset of participants, the advanced MRI images will be used for exploratory analysis.

Exploratory biomarkers related to Parkinson's disease, neurodegeneration (the central nervous system stops working properly), neuroinflammation (an inflammatory response within the brain or spinal cord), and immunogenicity related to the study vaccine will be assessed in any collected blood and/or samples of cerebrospinal fluid which is the fluid that is in the ventricles in the brain and surrounds the spinal cord within the skull and backbone.

Immunogenicity is the ability of a substance to enter a person's body and cause an immune response. An example of immunogenicity is a vaccination as it is intended with the study vaccine. It will be assessed using exploratory complementary methods on blood and/or samples of cerebrospinal fluid obtained by lumbar puncture in a laboratory.

Genetic Testing

You are being invited to take part in genetic testing as part of this study. This test is optional and should you chose not to participate in the genetic testing for this study it will not affect your ability to participate in this study. You will be provided with a separate Addendum called "Participant Information Sheet and Informed Consent Form Addendum: Optional Future Research, and Genetic Testing" by your study doctor who will be able to answer any questions that you might have on this test.

Genetic testing means an analysis of genetic material such as DNA (desoxyribonucleic acid), RNA (ribonucleic acid), chromosomes, proteins, or metabolites to see if the material detects genotypes (the genetic makeup of an organism), mutations (the changing of the structure of a gene), or chromosomal changes (these may alter the ability of a cell to survive and function). Genetic testing does not include testing that is directly related to a disease, disorder, or condition that has been diagnosed or could be diagnosed. Genetic information is the information that results from the analysis.

As part of this study, genetic material called RNA will be collected at week 0 (Visit 1) and week 74 (Visit 11). The role of RNA is to carry information from the DNA, where the protein-making machinery reads the RNA sequence and translates this information allowing the cell to grow. The collected material may be used for further understanding of the genetics of the disease and/or treatment response in the participating study populations. Neither you nor your study doctor will be given the results of the testing.

Other Assessments

Additional assessments on collected blood and urine samples may be performed during or after the study as far as the collected material is sufficient to perform the assessments. You will be asked if you agree to additional exploratory assessments and to the long-term storage of the samples remaining after the end of the study. Additional assessment(s) will be performed to better understand the study vaccine, Parkinson's disease, and/or related pathologies. No analysis will be performed on your samples or data without prior approval from a Research Ethics Committee and only with your prior approval in a separate consent form

As for the Genetic Testing, you will be invited to sign a separate Addendum for the optional Future Research if you agree. If you do not want to consent to these data collection, it will not have any impact on your participation in this study.

Some procedures that will be performed during the study may carry some risks as detailed in section 3 'Study Activities and Time Commitment', and your study doctor can provide more information to you.

You might experience adverse effects or discomforts that are not listed in the table above. Some adverse effects may not be known yet. New ones could happen to you. You must tell the study doctor or study staff right away if you have any problems.

Risks of Participation during Covid-19 Pandemic

Risks associated with acquiring Covid-19 infection by travelling to the hospital during a pandemic will be minimised as much as possible, with all local recommendations and restrictions followed. Visits to the hospital will be replaced by phone and/or home visits where this is considered appropriate to reduce the risk of acquiring Covid-19.

Please tell the study doctor or staff about all problems, illnesses, or injuries that happen to you during the study, even if you think they are not related to your taking part in this study.

4.0 Possible Side Effects

We do not know all the possible side effects of the study vaccine ACI-7104.056. Like all medicines, the study vaccine can cause side effects, although not everybody gets them. However, some people may experience serious side effects and may require treatment.

The study vaccine ACI-7104.056 has not been administered to any person prior to the start of this study.

However, a precursor (an earlier version of the vaccine in the development stages) of the study vaccine ACI-7104.056 has been tested in a phase 1 study series of 24 patients with early Parkinson's disease. This precursor vaccine contains the same ACI-7104.056 component that is responsible for the desired active effect (i.e. to target the pathological proteins). Most side effects observed during the precursor vaccine studies were mild to moderate, i.e. 74.6% of patients experienced mild side effects such as headache or fatigue and 20.6% of patients experienced moderate side effects such as a reaction at the injection site (irritation or swelling).

Local reactions at the injection site have also been observed in animal testing when using a similar medication to the study vaccine. Such reactions are expected for vaccine formulations containing aluminium hydroxide as an ingredient.

You will be closely monitored for the duration of your time in the study for any signs of possible side effects to the study vaccine. You should tell your study doctor about any changes in your health while taking part in the study.

5.0 What are the potential Benefits?

There is no guarantee that you will receive any benefit from taking part in this study. Your condition may remain the same, improve or could get worse. Information obtained from the study may help in the development of better treatments for early Parkinson's disease.

6.0 What if I/my partner falls pregnant during the study?

As the Sponsor does not know the effect of the study vaccine on an unborn baby, you or your partner should not become pregnant during the study. The effects of the study vaccine on a nursing infant are unknown. If you are pregnant or breastfeeding, you cannot participate in the study.

If you are capable of becoming pregnant (for a woman) or fathering a baby (for a man) then in order to prevent a pregnancy during the study, you and your partner must agree to use one of the following methods of contraception:

- Not having sexual intercourse is your preferred and usual lifestyle involves not having heterosexual intercourse
- Combined hormonal contraception – this is a form of hormonal contraception which combines both an oestrogen hormone and a progestogen hormone in varying forms: the pill, the patch, the vaginal ring, and an injection
- Progestogen-only hormonal contraception – this relies on progestogen hormones alone to prevent ovulation. There are several progestogen-only methods of contraception: pills, emergency pills, implants, injectables
- Intrauterine devices - a small often T-shaped contraceptive device that is inserted in the uterus
- Intrauterine hormone-releasing system - an intrauterine device that releases the hormone into the uterus
- Bilateral tubal occlusion - which means your fallopian tubes have been blocked
- Vasectomy (male sterilisation)

Female participants: if you are of a reproductive age, you must be willing to use highly effective methods of contraception from the screening visit until the end of their participation and will be asked to have a blood pregnancy test at screening, and a confirmation of the non-pregnancy status will be reassessed via urine pregnancy testing during the treatment and at week 100 to exclude the possibility of pregnancy.

Male participants: if you consent to take part in this study, unless you have had a vasectomy, you are required to use condoms with spermicide in addition to measures used by your female partner to prevent a pregnancy during the study and you must inform your partner of your participation in the study.

If you or your partner become pregnant during the study, you must tell your study doctor immediately.

7.0 What are my Responsibilities?

As a participant in this study, you have certain responsibilities. You will have to:

- Complete all required visits to the hospital or as home visits
- Tell the study doctor your full medical history
- Tell the study doctor of any side effects and changes or new medical problems you suffer during the study
- Tell the study doctor if you (or your partner) become pregnant

8.0 Will I be paid for participating in the study?

You will not receive any payment for taking part in the study. It is not expected to cost you to participate in the study. The study vaccine will be provided to you free of charge and you will not be charged for any procedure performed for this study.

You will be reimbursed for certain costs you acquire as a result of participating in this study (e.g., travel, meal etc.). Some expenses must be pre-approved. Please discuss expected costs with your study doctor. To receive reimbursements, expense-related receipts will need to be submitted at the time of your study visit..

9.0 What insurance is in place?

The Sponsor has taken out an insurance policy for the study. If you are injured or your health is affected, the insurance company will pay all reasonable and necessary medical costs to treat the injury or illness, if the injury or health issue was directly caused by the study vaccine or correctly performed study procedures.

Please note that taking part in this study may affect any personal insurance policies you have, such as health insurance, and you should contact your insurer to check if this is the case.

10.0 Do I have to participate and can I withdraw?

Your participation is voluntary and you can choose whether you want to take part in the study, and are free to change your mind at any time. If you decide not to take part, or stop taking part after the study has started, this will not affect your future treatment and care. If you want to withdraw from the study, you should contact your study doctor or study staff. Your study doctor may also decide that it is in your best interests to no longer take part in the study, or if you do not follow the instructions you receive for taking part in the study.

The Sponsor or Regulatory Authority may also decide to stop the study at any time for any reason.

If you decide to no longer take part in the study, or your study doctor decides you should no longer take part you will be asked to attend a last visit to ensure it is safe for you to no longer be monitored by the study doctor. You can discuss alternative treatments or follow-up measures with your study doctor if you stop participating in the study. You will not take part in the study after withdrawal.

If there is new information available on the study vaccine during the study which might make you change your mind about taking part in the study, you will be informed of this new information by your study doctor without delay.

11.0 What are the alternative treatments?

There is no current cure for Parkinson's disease, but medications may help control and improve your symptoms. Other treatments, e.g. L-Dopa, available may help you manage problems with walking, movement, muscle stiffness and tremor. These medications increase or substitute the reduced level of dopamine, a transmitter in the brain.

Most of these available treatments are not allowed to be used for more than 90 days. Your study doctor will discuss with you other treatments, including the benefits and risks, which are available for early Parkinson’s disease.

12.0 Who do I contact with questions or to report a possible study related injury or reaction?

If you have any questions about the study or your rights, at any time, or think you have experienced an injury or reaction to the study medicine, or if you have questions, concerns, or complaints about the research, you can ask your study doctor at any time.

Study Doctor/Principal Investigator: Dr [insert PI name and contact information]

For any questions about your rights as a research participant, please direct enquiries to <insert contact information for independent complaints service e.g. PALS or equivalent>.

Complaints:

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions [contact number]. If you remain unhappy and wish to complain formally, you can do this by contacting [insert details e.g. NHS Complaints Procedure or Private Institutional arrangements]. Details can be obtained from [insert details].

Harm:

The Sponsor 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).

The Sponsor will pay compensation where the injury probably resulted from:

- A study medication being tested or administered as part of the study protocol;
- Any test or procedure you received as part of the study

Any payment would be without legal commitment. (Please ask if you wish more information on this). We would not be bound by these guidelines to pay compensation where the injury resulted from a study medication or procedure outside the study protocol or where the protocol wasn't followed. Nor do the guidelines apply in the case of the study medication (or placebo) failing to have its intended effect.

You do not waive any of your legal rights by signing this form.

13.0 Confidentiality and Data Protection

The words in **bold** text are in a glossary of terms found at the end of this section for reference.

What **personal data** is being processed?

Your **personal data**, including your medical data, sex, age or date of birth, ethnicity, genetic data (including data from laboratory samples) will be collected during the study. Only **personal data** needed to run the study properly and safely will be collected.

Who will be able to see your **personal data** and how will it be protected?

The Sponsor and those working on the study will only be given as much information from your medical records as is needed for the correct running of the study.

Coded Data

Your **personal data** is safeguarded by giving it a **participant ID number** and is called **coded data**. Your c**oded data** will be accessed by people who are working for or on behalf of the Sponsor and its **affiliates** in connection with the study and external people such as the regulatory authorities which reviewed and approved the study.

They will not be given your name, where you live or anything that could identify you. Your medical data and any samples will be labelled with your **participant ID number only**. Your **coded data** will be stored and analysed under the **participant ID number**. In the case of emergency, the study site can trace the information back to you.

The Sponsor is responsible for all your **coded data** collected during the study and will act as the **data controller**. They are responsible for making sure all those working on the study comply with the data protection requirements for the collection, use and processing of **personal data** collected for this study. As a Pharmaceutical company the Sponsor have a legitimate interest in using information relating to your health care when you agree to take part in a research study. This means that the Sponsor will use your data collected in the course of a research study in the ways needed to conduct and analyse the research study.

Non-coded data

The **non-coded data** will be recorded by the study doctor in your medical records and medical chart and remain the responsibility of the study doctor.

To make sure the study is run properly and ensure data is recorded correctly it may be necessary for the following people to look at your **non-coded data**.

- Specific authorised employees of the Sponsor and persons acting on the Sponsor's behalf who are working on the study
- Representatives of any **Regulatory Authority**

These people may view your medical records remotely (from a location outside of the study center).

How long will your **coded data** be kept for?

The **coded data** will be kept for up to 25 years once the study has finished. It may be used and shared for similar future research purposes related to the use of ACI-7104.056 but your privacy would continue to be protected as only **coded data** would be used. Your identity will be kept confidential unless it is provided with your agreement.

Can you see the **personal data** collected and recorded about you?

You can speak with the study doctor to see your **personal data** that has been collected and to have any inaccurate information about you corrected. If you decide to stop taking part in the study it is important to understand that your **coded data**, collected up until the date when you stop taking part in the study, will remain as part of the study records and cannot be deleted. No new data will be collected and processed. To safeguard your rights, we will use the minimum personally-identifiable information possible.

If you have concerns about the way your **personal data** has been used, please contact your study doctor, who may contact the Sponsor's data protection officer if needed dpo@acimmune.com or the Sponsor's Data Representative if needed.

If you are not happy with the sponsors response or believe the sponsor is processing your data in a way that is not right or lawful, you can complain to the Information Commissioner's Office (ICO) (www.ico.org.uk or 0303 123 1113).

Where will your **personal data** be sent?

The Sponsor or their representative may need to send your **coded data** to other countries, including the USA, where the data protection laws may not be as strict as in your country. The reason for sending the data is to support data analysis and applications to market new medicines made by the Sponsor. The Sponsor is required to protect your privacy and send any **coded data** in a secure way as required by law. You can ask them to provide more information about this through your study doctor.

Where will study information be made publicly available?

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 Website at any time.

Affiliate	A person or organisation officially attached to the Sponsor, for example the Sponsor offices in other countries
ClinicalTrials.gov	ClinicalTrials.gov is a US database of clinical studies conducted around the world. Information like the purpose of a study, timelines, status, results, etc. can be searched on this website
Coded Data	The participant is allocated an identification number and all data and samples related to that participant are held under this number.
Data Controller	The company, in this case, the Sponsor who is responsible for looking after your information and using it properly.
Participant ID number	Identification number allocated to you that is included in the research study.
Non-coded data	Data which may directly identify you including parts of your medical records and charts relevant to the study.
Personal Data	Any information that can directly identify you, such as full name, address, date of birth, health information such as non-coded data or indirectly, such as coded data.
Regulatory Authority	A regulatory authority is a government agency set up to enforce safety and standards and to protect participants.

14.0 Where can I learn more about the study and study results?

A description of this study will be available on www.ClinicalTrials.gov as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results with anonymous data. You can search this website at any time.

About 12 months after completion of the study, the study results and a summary in which you cannot be identified will be available to you in the EU database.

15.0 Will my GP be informed?

The study doctor/staff will let your regular doctors, including your GP, know that you are in this study and may report any side effects. It is important for your other doctors to know that you are taking a study medication.

This is done to make sure that your GP and/or other healthcare professional can best manage your overall healthcare. This can be done by providing information, for instance, about medications that should not be prescribed to you while you are on the study.

They may be asked to provide details from your medical record including any additional treatment received during the study.

To be Printed on Hospital/Institute Headed Paper

Participant Information Sheet and Informed Consent Form

Study Title:	An adaptive, Phase 2, double-blind, randomized, placebo-controlled, multicenter study to evaluate the safety, tolerability, immunogenicity, and pharmacodynamic effects of ACI-7104.056 in patients with early stages of Parkinson's disease
Protocol Number:	ACI-7104-PD-2103
EU CT Number:	2022-500292-31-00
IRAS ID:	1006102
Sponsor:	AC Immune SA EPFL Innovation Park - Building G CH-1015 Lausanne, Switzerland
Principal Investigator /Study Doctor:	<Print name of Principal Investigator>
Site Number:	<Site Number>
Site Name and Address / Study Centre:	<Site Name and Address>
Site Phone Number:	<Insert Site Telephone Number>

By signing below you are confirming that you have read the participant information sheet and this informed consent form and understand it.

I declare the following:

YOUR CONSENT	**PLEASE INITIAL EACH BOX**
I confirm that I have read the Participant Information Sheet dated <insert date> (version <insert version>) for the above study and I have been given enough time to consider the information, ask questions about the study and my questions have been answered to my satisfaction.	Please Initial
I understand that I am taking part in this study voluntarily and I can withdraw from the study at any time without giving any reason, without penalty, losing any benefits and without my medical care or legal rights being affected.	Please Initial
I understand that my participation in the study will involve the collection, use and disclosure of information about me, my health and my participation in this study as described in the participant information sheet. I agree to this.	Please Initial
I understand that relevant sections of my medical notes and data collected during the study, may be looked at by individuals authorised by sponsor, from 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	Please Initial
By initialing this statement, I understand that my coded Personal Information can be used for the study as explained in the participant information sheet. I understand that if I do not initial this statement, I will not be able to participate in this study.	Please Initial
I understand to the transfer of my coded personal information and samples to recipients located outside of the United Kingdom in countries that do not have data protection or privacy laws that offer the same level of protection as the data protection and privacy laws in this country, as described in the participant information sheet.	Please Initial

I understand that my coded personal information can be used for additional scientific research related to my disease or similar diseases and/or development of the study medication (but at all times in compliance with applicable law and regulation). I understand that I can still participate in the study even if do not initial this statement	Please Initial
I agree that my own doctor (GP) and/or other healthcare professional will be told about me taking part in this study and they may give the study doctor information about my health.	Please Initial
I understand that the information held and maintained by the Health and Social Care Information Centre and other central UK NHS bodies may be used to help contact me or provide information about my health status.	Please Initial
I understand that the information collected about me will be used to support other research in the future, and may be shared anonymously with other researchers.	Please Initial
I understand I will receive/will be given access to a fully signed and dated copy of this consent form.	Please Initial
I agree to take part in this study	Please Initial

Signatures

Participant	
	Print Name
Signature	Print Date
Name and Contact Details of Participant's GP:	

Study Personnel Performing Consent	
	Print Name
Signature	Print Date

When completed, one copy for participant; one copy for study doctor site file; one (original) to be kept in medical notes.