Participant Information Sheet and Informed Consent Form

Participant Information Sheet

Protocol No. DSP2505-CT4

Protocol Appendix 1

Dasan Pharmaceutical Co., Ltd.

Core ICF V3, 18 November 2025

Clinical study title: A Multi-center, Randomized, Double-blind, Active control, Parallel, Phase 4 Clinical Trial to Evaluate the Efficacy and Safety of CANIUM Tab. in Acute Bronchitis Patients.

Participant screening number: _____

This information sheet provides the information you (or your child*) need to decide whether to participate in the clinical study you have been invited to join.

*For participants aged 12 years or older and under 19 years, the legally authorized representative (guardian) will also be asked to sign this participant information sheet and informed consent form. Accordingly, the terms “participant” and “you” below may refer to the participant aged 12 years or older and under 19 years, namely the child of the legally authorized representative (guardian) signing this form.

Before agreeing to participate, it is important that you carefully read the following information and clearly understand the study and the potential benefits and risks of participation. The investigational drug used in this study, CANIUM Tab., is marketed by Dasan Pharmaceutical Co., Ltd. for the treatment of acute bronchitis. It has been approved for marketing by the Ministry of Food and Drug Safety (MFDS). This study is being conducted to demonstrate its noninferiority to the comparator, Umckamin Tab., which contains the same active ingredient.

This information sheet describes the purpose and procedures of the study, anticipated benefits and risks, possible discomforts, your responsibilities, and your rights. Please take sufficient time to read it. You may discuss it with your family or other people. If anything is unclear or you have questions, you may ask the investigator or study staff at any time for a detailed explanation. After receiving an explanation and considering the information carefully, please decide whether to participate. Your participation is entirely voluntary, and you may refuse to participate. If you decide to participate, you or your representative will sign the consent form. After signing, you will receive one copy of this information sheet and the signed consent form. Signing this form does not defer or limit your rights.

1. Purpose of the clinical study

According to the 2023 health insurance medical care statistics in the Healthcare Big Data Open System, acute bronchitis is the second most common condition in outpatient care, affecting more than 16 million patients annually in Korea.

Acute bronchitis is caused by inflammation of the bronchial mucosa. Viral infections, such as influenza virus and adenovirus infections, are the most common cause; secondary bacterial infection may also occur in fewer than 10% of cases. Noninfectious causes include cold air, dust, airway irritants, and harmful gases. Acute bronchitis is an acute respiratory illness lasting approximately 1 to 3 weeks, mainly characterized by cough with or without sputum. Mucosal injury and inflammatory mediators may act together to cause transient airway obstruction or bronchial hyperresponsiveness; reduced lung function may accompany cases caused by pneumonia.

Although antibiotics are often used when acute bronchitis is diagnosed, the presence or absence of colored sputum does not clearly distinguish bacterial from viral lower respiratory tract infection. Because most acute bronchitis is viral, antibiotic treatment is not clinically recommended. Treatment should therefore aim to reduce antibiotic use and improve the condition of patients with acute bronchitis.

Symptomatic treatment is the first-line approach to cough caused by acute bronchitis. Antitussives such as codeine or dextromethorphan may be given for a short period. Herbal preparations containing Pelargonium sidoides extract are also prescribed to reduce symptoms of acute bronchitis in adults and people aged 12 years or older.

CANIUM Tab. (Pelargonium sidoides 11% ethanol dry extract [5.5-6.6:1]) contain an herbal extract derived from dried Pelargonium sidoides roots. They are a generic medicine of Hanwha Pharma's marketed Umckamin Tab. (a mixture [1:4.56] of Pelargonium sidoides 11% ethanol extract [1:8-10] and maltodextrin). A generic medicine has the same ingredients, strength, indications, and effects as an original medicine whose patent has expired.

Based on this background concerning the indication and its treatment, the purpose of this study is to demonstrate the noninferiority of CANIUM Tab., a generic medicine with equivalent or better efficacy and safety results in pharmaceutical equivalence testing, compared with Umckamin Tab. in patients with acute bronchitis aged 12 to 75 years, inclusive.

2. Information about the study drugs and assignment to the test or control group

2.1 Information about the study drugs

The drugs used in this study are CANIUM Tab. (test drug) and Umckamin Tab. (comparator).

If you participate, you will take two tablets by mouth per dose, three times daily for 7 days. The test group will receive one test-drug tablet and one placebo tablet matching the comparator. The control group will receive one comparator tablet and one placebo tablet matching the test drug.

A placebo is an inactive tablet made to look identical to the real medicine so that it cannot be distinguished from it. It is taken together with the real medicine to prevent you and the investigator from knowing your assigned group.

2.2 Assignment to the test or control group

You have an equal, 50:50 chance of assignment to either group. Assignment is random, using a computer-generated randomization list that arranges the two groups in an unpredictable order while maintaining equal allocation. For example, assignment occurs by chance, like heads or tails in a coin toss. This is a double-blind study: neither you nor the investigator can choose or know the group to which you are assigned.

3. Expected number of study participants

This study will be conducted at < > institutions in Korea. The overall target enrollment is approximately 218 participants, with 109 in each group.

4. Study methods and expected duration of participation

If you participate, you will attend three visits over approximately 1 to 2 weeks, with a minimum of 6 days and a maximum of 10 days.

Visit 1	Visit 2	Visit 3
Within 2 days before Day 0	Day 0	Day 7 (±1 day)
Screening	Baseline; randomization; start of study drug administration	End-of-study visit; efficacy and safety assessments

5. Tests and procedures at each visit

The following procedures will be performed at each visit.

Visit 1 (within 2 days before Day 0; screening)

If you agree to participate, the following procedures will be performed at the first (screening) visit. Screening may be completed at this visit or within 2 days.

- Your demographic information, including date of birth, sex, alcohol use, and smoking history, will be collected.
- Your medical history, including surgery within the previous 6 months, and medication history within the previous month (30 days) will be reviewed. Some medical and medication history may be reviewed over the periods required by the individual eligibility criteria.
- A physical examination will be performed.
- Your blood pressure, tympanic temperature, and heart rate will be measured.
- An electrocardiogram (ECG) will be performed to check heart function.
- A chest X-ray will be taken to check for lung and heart disease.
- Your height and weight will be measured.
- Blood and urine tests will be performed to assess your general health.
- If you are a woman who could become pregnant, a urine or blood pregnancy test will be performed.
- The Bronchitis Severity Score (BSS) will be assessed to determine the severity of your acute bronchitis symptoms.
- The inclusion and exclusion criteria will be checked.
- Your next visit will be scheduled.

Visit 2 (Day 0; randomization)

This visit will take place within 2 days after the first visit. If the results obtained at Visit 1 allow final confirmation of eligibility that day, Visits 1 and 2 may take place on the same day. Procedures required at both visits will then be performed only once.

- Changes in your medical and medication history since the previous visit will be checked.
- A physical examination will be performed.
- Your blood pressure, tympanic temperature, and heart rate will be measured.
- The BSS will be assessed to determine the severity of your acute bronchitis symptoms.
- The Cough Assessment Test (COAT) will be performed.
- The screening results from the previous visit will be reviewed to make a final assessment of your eligibility.
- If you are eligible, you will be assigned a randomization number.

- The investigator will prescribe the study drugs and explain how to take them.
- Your next visit will be scheduled.

Visit 3 (Day 7 ±1 day; end-of-study visit)

This is the final study visit, when final efficacy is assessed after you have completed all study drug administration. The visit window is 1 day before or after the scheduled date. The same procedures will also be performed if you discontinue the study early.

- Changes in medication use since your previous visit will be checked.
- All adverse events since your previous visit will be reviewed. You must tell the investigator about all abnormal physical symptoms experienced after taking the study drugs.
- A physical examination will be performed.
- Your blood pressure, tympanic temperature, and heart rate will be measured.
- An ECG will be performed to check heart function.
- Blood and urine tests will be performed to assess your general health.
- If you are a woman who could become pregnant, a urine or blood pregnancy test will be performed.
- The BSS will be assessed to determine the severity of your acute bronchitis symptoms.
- The COAT will be performed.
- The investigator will assess overall improvement in response to treatment using the Integrative Medicine Outcome Scale (IMOS).
- Your satisfaction with the treatment effect will be assessed using the Integrative Medicine Patient Satisfaction Scale (IMPSS).
- Remaining study drugs will be collected, counted, and recorded.
- You will return all unused study drugs and empty packaging from the study drugs you have taken.

Unscheduled visits

An additional visit may take place at your or your representative's request, or if the investigator considers it necessary. An unscheduled visit must not change the scheduled visit timetable.

At an unscheduled visit, changes in medication use and the occurrence of adverse events will be checked. Additional tests may be performed as the investigator considers necessary.

6. Possible risks and discomforts from participating

6.1 Expected adverse events and risks of the study drugs

The approved labeling for CANIUM Tab. and Umckamin Tab. includes the following adverse events and risks.

1) Adverse events

1. Gastrointestinal disorders such as stomach pain, heartburn, nausea, and diarrhea may occur occasionally.

2. Mild gum bleeding or nosebleeds may occur rarely.

3. Hypersensitivity reactions such as rash, hives, and itching of the skin or mucous membranes may occur rarely.

4. Severe hypersensitivity reactions such as facial swelling, difficulty breathing, and decreased blood pressure may occur very rarely.

5. Increased liver enzyme levels may occur occasionally. Inflammatory liver disease has also occurred in some patients.

6. Decreased platelet counts have been observed during treatment, although this may be caused by an underlying disease.

7. In Korean postmarketing surveillance of liquid and syrup formulations containing the same active ingredient, the incidence of adverse events, regardless of causality, was 0.47% (3 events in 3 of 641 patients). No adverse drug reactions for which a causal relationship could not be excluded were reported. No serious adverse events or unexpected adverse drug reactions were reported.

8. Among overseas reports involving liquid and syrup formulations with the same active ingredient, liver injury and hepatitis have been reported in association with use of this medicine. Because these reports were spontaneous, reliable conclusions have not been established.

2) General precautions

1. Stop taking the medicine immediately if signs of liver injury occur, such as jaundice, dark urine, severe upper abdominal pain, or loss of appetite.

2. Stop taking the medicine if your condition does not improve within 1 week, fever persists for several days, or symptoms such as difficulty breathing or blood-streaked sputum do not improve.

3. Do not take the medicine while lying down.

6.2 Discomforts caused by tests

Blood pressure: Your blood pressure will be measured on your arm after you have been seated for 5 minutes. You may feel some discomfort while the cuff inflates.

Blood tests: Blood collection may cause slight pain, bruising, bleeding, temporary discomfort, mild dizziness, and, rarely, infection at the needle site. If possible, you should fast for at least 8 hours before the blood test.

Electrocardiogram: Small electrode sensors will be attached to your chest to measure your heart's electrical activity, and you will need to lie down for a few minutes. The sensors may cause local irritation or discomfort when removed.

Chest X-ray: Your chest will be X-rayed to assess conditions such as lung and heart disease. This involves exposure to a small amount of radiation. Radiation exposure in everyday life is approximately 2-5 millisieverts (mSv) per year. A plain diagnostic X-ray exposes you to approximately 0.1 mSv, a small amount equivalent to about 10 days of everyday exposure; you need not worry about side effects from this radiation exposure.

7. Samples collected and their storage

Blood: Blood tests will be performed at two visits during the study. Approximately 7-10 mL of blood will be collected from a vein in your arm each time.

Urine: Urine tests will be performed at two visits during the study.

Sample storage: After testing at the study site, all blood and urine samples will be promptly discarded in accordance with the site's sample management procedures. The results of study-related tests will be used only for this study.

8. Participant responsibilities

You must follow these requirements to protect your safety and ensure that the study is conducted accurately.

1. Follow the study drug dosing schedule: two tablets per dose, three times daily, by mouth.

2. Attend all scheduled visits and tests. For Visit 3, if possible, fast for at least 8 hours before coming to the site; do not eat or drink anything except water.

3. Tell the investigator about all unwanted physical or mental changes you experience after taking the study drugs.

4. Before taking any medicine other than those prescribed by the investigator or starting a new treatment during the study, tell the investigator about that medicine or treatment.

5. In particular, the following medicines are prohibited or permitted during this study. You may ask the investigator for a detailed explanation at any time.

Prohibited concomitant medications

1. From Visit 1 through the end-of-study visit (Visit 3): anticoagulants.

2. From 2 weeks before Visit 2 through Visit 3: systemic antibiotics and antivirals; systemic or inhaled glucocorticosteroids.

3. From 1 week before Visit 2 through Visit 3: angiotensin-converting enzyme inhibitors (ACEIs). For perindopril, the prohibited period starts 4 weeks before Visit 2. However, participants already taking an ACEI for an underlying disease may continue it without changing the dose or regimen during the study.

4. From 2 days before Visit 2 through Visit 3: expectorants (mucolytics or sputum-expelling agents), antitussives, and herbal preparations with antitussive or expectorant effects.

5. Throughout the study (Visits 1-3): antihistamines; anticholinergics, including bronchodilators; other symptomatic treatments for acute bronchitis; and analgesics. Temporary use of acetaminophen for fever, up to 1.5 g/day, is permitted, but it must not be taken within 24 hours before Visits 2 and 3.

Permitted concomitant medications

1. Medicines used before enrollment that, in the investigator's judgment, are not expected to affect interpretation of the study results.

2. Medicines used temporarily to treat other diseases or adverse events, after consultation with the investigator.

3. Temporary acetaminophen use for fever, up to 1.5 g/day, except within 24 hours before Visits 2 and 3.

6. Keep the study drugs safely out of children's reach, and do not allow anyone else to take them. Return any remaining study drugs at each visit.

9. Pregnancy

The safety of CANIUM Tab. and Umckamin Tab. in pregnant women has not been established. Their effects on a fetus, pregnant woman, or breastfed child are unknown. You cannot participate if you are planning pregnancy, are pregnant, or are breastfeeding.

If you are a woman who could become pregnant, you must agree to use an acceptable method of contraception throughout the study.

All women who could become pregnant will undergo pregnancy testing before study drug administration. The test may not detect an early pregnancy. Pregnancy testing will be performed at Visits 1 and 3. If pregnancy is confirmed during the study, notify the investigator immediately. For your safety, you will discontinue the study. The investigator will ask you to provide pregnancy-related information, including your medical and obstetric history, medications used before pregnancy, and information about the pregnancy. The investigator will follow the pregnancy outcome (for example, delivery or early termination) and the child's health through delivery, and will provide pregnancy information to the sponsor and institutional review board. Your child's name will not be collected at delivery. Information will be managed as described in Section 16, Collection and Use of Personal Information and Confidentiality.

Acceptable methods of contraception are: combined hormonal contraception containing estrogen and progestogen that inhibits ovulation (oral, intravaginal, or transdermal); progestogen-only hormonal contraception that inhibits ovulation (oral, injectable, or implantable); an intrauterine device (IUD); an intrauterine hormone-releasing system (IUS); bilateral tubal ligation or salpingectomy; bilateral oophorectomy; a vasectomized partner; and sexual abstinence.

10. Possible benefits and potential risks of participation

Your acute bronchitis may improve during this study, or participation may provide no direct benefit to you.

If the study results are positive, they will demonstrate that the efficacy and effects of CANIUM Tab. do not differ substantially from those of Umckamin Tab., helping patients with the same disease continue to be prescribed and take this medicine in the future.

Known side effects and unexpected adverse events may occur with study drug use. See Section 6.1 for details. To protect participants, people at increased risk of side effects will be excluded according to the inclusion and exclusion criteria. Your condition will be closely monitored during the study so that appropriate measures can be taken when necessary.

11. Costs of participation

If you participate, you will not have to pay for study-related medical care or tests, including ECGs, chest X-rays, and laboratory tests, during the study. The study drugs will be provided. However, you will be responsible for hospitalization, consultation, and other costs unrelated to the study.

You will also receive a transportation allowance of KRW OOO at each visit in consideration of your time and travel expenses. Participants who withdraw consent or discontinue for another reason will receive transportation reimbursement in proportion to the duration of their participation.

12. Alternative treatments and their potential risks and benefits

Apart from the study drugs, symptomatic treatment is generally used as first-line treatment for acute bronchitis. Antitussives such as codeine or dextromethorphan, expectorants, or beta-2 bronchodilators may be tried for a short period.

Codeine is an opioid antitussive that can cause drowsiness, dizziness, and vomiting even with short-term use. Dextromethorphan suppresses cough by acting on the cough center in the brain; rare side effects include dizziness, rash, redness, nausea, vomiting, and loss of appetite. Codeine and dextromethorphan require caution when used with other medicines. If you take other medicines, their use should be considered carefully. Beta-2 bronchodilators may relieve respiratory symptoms in the short term, but regular use may increase the risk of worsening symptoms.

Antibiotics are also commonly used, but they are not effective for treating acute bronchitis and may contribute to inappropriate antibiotic use.

If you do not participate, you may continue to receive care from the investigator, and your treatment will not be adversely affected. If you withdraw from or complete the study, the investigator will advise you on continuing treatment for your disease using existing treatments.

13. Withdrawal after giving consent

Participation is entirely voluntary. You may stop participating at any time by telephone or in person and may receive other established treatments after stopping. Refusal to participate or withdrawal will not result in any disadvantage or harm. If you withdraw consent, human biological samples (blood and urine) collected before withdrawal will be discarded after analysis in accordance with laboratory procedures. No new health information will be collected after withdrawal. However, Dasan Pharmaceutical Co., Ltd. will use all information collected from you before withdrawal as study information.

If the investigator learns of new facts or information that could affect your decision to participate, you will be informed whenever such information becomes available during the study.

14. Reasons participation may be stopped during the study

You may have to stop participating early or be withdrawn in the following circumstances:

1. You or your representative withdraw consent.

2. A violation of the inclusion or exclusion criteria is discovered during the study.

3. An adverse event or serious adverse event makes continued participation difficult.

4. You or your representative request discontinuation because the treatment effect is unsatisfactory.

5. You do not follow the instructions of the principal investigator or other investigators.

6. You cannot be contacted for follow-up.

7. You become pregnant during the study.

8. The sponsor or investigator otherwise considers continued participation inappropriate.

9. You take a prohibited concomitant medication that may affect efficacy or safety assessments.

If you discontinue early or are withdrawn, the investigator will guide you through the procedures performed at the final efficacy assessment visit. No further information will be collected for this study. Information collected before discontinuation will be used only for this study.

The entire study or the study at a particular site may also end early if efficacy or safety information materially affects continuation, if a site or investigator violates the protocol, contractual obligations, or applicable laws and regulations, or if the target enrollment cannot be achieved.

15. Compensation and treatment for injury

The medical team will make every effort to protect your safety. If an adverse drug reaction occurs, prompt and appropriate measures will be taken to minimize the adverse event as far as possible.

If you suffer an injury related to study drug administration, including either the test drug or comparator, or to study procedures, compensation will be provided in accordance with the sponsor's compensation policy, and you will receive the best treatment possible. Compensation will depend on factors such as the severity and persistence of the injury.

The following are excluded from compensation:

1. Injury from adverse events caused by investigational products not commissioned or supplied by Dasan Pharmaceutical Co., Ltd.

2. Failure of the study drugs to provide the expected effect or benefit.

3. Injury for which a causal relationship to participation is not recognized.

4. Failure to provide therapeutic benefit to participants receiving placebo.

5. Injury from usual complications arising from worsening or progression of the disease.

6. Injury from accidents or similar events considered likely to have occurred even without study participation.

7. Cases in which the principal investigator provides appropriate medical treatment for an injury and the participant recovers.

8. Injury caused by the participant's or guardian's failure to follow the principal investigator's instructions or the protocol, intentional misconduct, or gross negligence.

9. Injury caused by intentional misconduct, negligence, or failure to fulfill duties by the principal investigator or other investigators.

10. Injury caused by continued study drug administration after the study ends.

If participation causes any risk, discomfort, or injury, contact the study staff at this institution listed in Section 17.

Dasan Pharmaceutical Co., Ltd. will handle compensation as follows:

1. When the principal investigator or participant requests compensation, the company will document and receive the request, determine eligibility and the amount of compensation, notify the participant of its decision within 15 days of the request, and check whether the participant objects.

2. If the participant does not object within 15 days after receiving the decision, both parties will be understood to have agreed to the compensation.

3. If the parties disagree on the amount, it will be determined with advice from a neutral third party acceptable to both parties, and compensation will be provided accordingly.

16. Collection and use of personal information and confidentiality

All records concerning your identity collected during this study will be coded before they are sent outside the study site to protect your confidentiality. The same code will identify you in all study-related documents. Your identity will remain confidential in study publications, presentations, and published results.

Your personal and sensitive information will be collected and used to conduct the study and to compile, analyze, and report its results.

Your data will be strictly protected under the Personal Information Protection Act and other applicable laws. During and after the study, the third parties listed below may review your medical records and receive data, within the limits necessary to protect your confidentiality, to verify study procedures and data quality in accordance with applicable laws.

- Recipients of data and persons permitted to review medical records: Dasan Pharmaceutical Co., Ltd.; CLIPS BnC Co., Ltd.; investigators and study staff; study auditors; the study site's institutional review board; and the MFDS.
- Recipient of data: Medisafe Co., Ltd., which manages safety information for the study drugs.

By signing the consent form, you or your representative authorize this access. Your identifying personal information will nevertheless be protected. The data will not reveal who you are or where you live. If you believe you have suffered an injury related to the study drugs, the investigator may also provide your health information to the sponsor's insurer.

Your personal and sensitive information will be retained and used for 5 years after study completion, then destroyed. During the same period, the third parties listed above may retain and use your information for purposes related to the study. The retention period may be extended if directed by the Commissioner of the MFDS or considered necessary by the sponsor.

You are free to decide whether to agree to the collection and use of this information and may stop participating at any time. Refusing to agree will not disadvantage you in receiving medical care or prescriptions.

17. Study personnel and contact details

If you would like further information, suffer a study-related injury, or need to contact the investigator for medical reasons, you or your representative may telephone the following contacts at any time.

Study site: _____

Principal investigator: Name and affiliation _____ Telephone _____

Study staff/coordinator: Name and affiliation _____ Telephone _____

If you or your representative have questions about ethical matters or your rights, contact:

Official name of the institutional review board: _____ Telephone _____

Participant Informed Consent Form

Clinical study title: A Multi-center, Randomized, Double-blind, Active control, Parallel, Phase 4 Clinical Trial to Evaluate the Efficacy and Safety of CANIUM Tab. in Acute Bronchitis Patients.

I (or the participant's legally authorized representative [guardian], as applicable throughout this form) confirm that I have had sufficient time to read and understand the participant information sheet.

[ ] The investigator has explained all study information to me in detail. I have had the opportunity to ask questions and am satisfied with the answers.

[ ] I agree to participate of my own free will. I understand that I may refuse to continue or freely withdraw at any time for personal or other reasons, without any disadvantage in medical care or otherwise.

[ ] I understand that I may contact the investigator or institutional review board at any time with questions about the study. I consent to direct access to my medical records solely for study purposes.

Consent to the collection, use, and provision of personal and sensitive information

Item	Details
Personal information collected	Date of birth, age, sex
Sensitive information collected	Medical and medication history; health information including study-related test results; contraception information; for women, childbearing potential and pregnancy information
Purpose of collection and use	Evaluation of the participant's treatment status, efficacy, and safety; quality assurance of study procedures and data
Retention and use period	5 years after study completion
Recipients	Dasan Pharmaceutical Co., Ltd.; CLIPS BnC Co., Ltd.; investigators and study staff; study auditors; the study site's institutional review board; MFDS; Medisafe Co., Ltd.

You may refuse the collection, use, and provision of the personal and sensitive information listed above. However, if you refuse, you cannot participate in this study.

[ ] I understand and agree to the collection and use of personal information and its provision to third parties.

[ ] I understand and agree to the collection and use of sensitive information and its provision to third parties.

For participants in vulnerable circumstances

[ ] I understand that I am a participant in vulnerable circumstances. Nevertheless, I voluntarily inquired about this study and decided to participate without being influenced by others.

To be completed by the participant or representative

Person	Name	Signature	Date (YYYY/MM/DD)
Participant	_____	_____	_____
Representative, if applicable	_____	_____	_____

Reason for representative consent and relationship to the participant:

_____

For participants aged 12 years or older and under 19 years, consent from the legally authorized representative (guardian) is required. The legally authorized representative should enter only the minor participant's name in the “Participant name” field. Consent to participation from participants aged 12 years or older and under 19 years will be obtained using a separate consent form.

To be completed by the impartial witness

[ ] By signing below, I confirm that the consent form, participant information sheet, and all other study-related information were accurately explained to the participant or representative and that they understood the consent form. The entire consent process took place of the participant's or representative's free will.

Witness name, if applicable: _____ Signature: _____ Date (YYYY/MM/DD): _____

Witness affiliation and reason for attendance: _____

To be completed by the investigator

[ ] I have fully explained the study information to the participant named above and confirmed that the participant voluntarily agreed to participate. I will provide the participant with one copy of the information sheet and the signed and dated consent form.

Investigator name: _____ Signature: _____ Date (YYYY/MM/DD): _____