Buddhist Tzu Chi Medical Foundation Hualien Tzu Chi Hospital Informed Consent Form for Clinical Trial Participants

蓋本委員會戳章
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Revised Version of the Research Ethics Committee Meeting on November 28, 2023

Project Title：

Esophageal visceral hypersensitivity and hypervigilance in disorders of gut-brain interaction: the roles of neuromodulators and cognitive-behavioral therapy

Study Institution： Buddhist Tzu Chi Medical Foundation Hualien Tzu Chi Hospital Department of Gastroenterology	Sponsor/Pharmaceutical Company：None Source of Research Funding: Hualien Tzu Chi Hospital

Principal Investigator: Dr. Wei-Yi Lei	Department/Title: Department of Gastroenterology / Attending Physician
Co-Principal Investigator: Dr. Chien-Lin Chen	Department/Title: Department of Gastroenterology / Director
Co-Principal Investigator: Dr. Ming-Wen Weng	Department/Title: Department of Gastroenterology / Attending Physician
Co-Principal Investigator: Dr. Chih-Hsun Yi	Department/Title: Department of Gastroenterology / Attending Physician
Co-Principal Investigator: Dr. Tso-Tsai Liu	Department/Title: Digestive Function Testing Department / Director
Co-Principal Investigator: Dr. Rui-Sheng Hong	Department/Title: Department of Gastroenterology / Attending Physician
Co-Principal Investigator: Dr. Chun-Wei Wang	Department/Title: Attending Physician, Department of Gastroenterology, Kaohsiung Medical University Hospital
Co-Principal Investigator: Dr. Shu-Wei Liang	Department/Title: Attending Physician, Department of Gastroenterology, Chung Shan Medical University Hospital
Co-Principal Investigator: Dr. Wen-Lun Wang	Department/Title: Director, Department of Gastroenterology, E-Da Hospital
Co-Principal Investigator: Dr. Ming-Tsung Hsieh	Department/Title: Attending Physician, Department of Gastroenterology, National Cheng Kung University Hospital

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Co-Principal Investigator: Professor Yi-Mei Lin	Department/Title: Professor, Department of Psychology, Kaohsiung Medical University
Co-Principal Investigator: Dietitian Hui-Min Lin	Department/Title: Clinical Nutrition Division, Department of Nutrition / Dietitian
Researcher: Psychotherapist Pei-Yun Lin	Department/Title: Psychotherapist, Yuli Hospital
Researcher: Counseling Psychologist Ssu-Ting Hsu	Department/Title: Counseling Psychologist, Secret Garden Counseling Center
Researcher: Dietitian Chen-Ying Su	Department/Title: Clinical Nutrition Division, Department of Nutrition / Dietitian
24-Hour Project Contact: Wei-Yi Lei	Phone: 0970-339629

Participant's Name：	Medical Record Number：

You are being invited to participate in this clinical trial. This form provides you with relevant information about the study. The principal investigator or authorized personnel will explain the details of the trial and answer any questions you may have. Please do not sign this consent form until all your questions have been satisfactorily answered. You are not required to make an immediate decision about whether to participate. Please take the time to carefully consider your decision before signing. You must sign the consent form in order to participate in this trial. If you agree to participate, this document will serve as a record of your consent. Even after you provide your consent, you can withdraw from the trial at any time without providing any reason.

(1) Study Purpose：

This study is a multi-center clinical trial conducted in Taiwan. This consent form is for Study 1. We will recruit participants from five medical centers in Taiwan, including 210 participants from our hospital and 400 participants from other centers (120 from National Cheng Kung University Hospital, 120 from Kaohsiung Medical University Hospital, 120 from E-Da Hospital, and 40 from Chung Shan Medical University Hospital), with a total of 610 participants expected. The purpose of this study is to investigate the efficacy of neuromodulators in treating esophageal-brain-gut axis communication disorders and the role they play in these conditions. We will further compare the efficacy of neuromodulators across different subtypes of esophageal-brain-gut axis communication disorders. Additionally, we will explore the differences in treatment outcomes with different types of neuromodulators for these disorders.

All treatments carry some risks, and clinical trials are no exception. Please carefully consider your decision before deciding whether to participate in this study.

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(2) Background of the Study or Current Status of the Drug/Medical Technology/ Medical Device:

Tricyclic antidepressant (TCA)

The main ingredient of tricyclic antidepressants (TCA) is imipramine HCl. Imipramine has various pharmacological effects, including α-adrenergic antagonism, antihistaminic, anticholinergic actions, and blocking of the 5-HT3 receptor. The mechanism of action of imipramine as an antidepressant is unknown, but it is thought to primarily inhibit the reuptake of norepinephrine (NA) and serotonin (5-HT) in the brain, without involving a stimulant effect on the central nervous system.

(1) Product Name:：Jing'an Film-Coated Tablets 25 mg

(2) Indications/Intended Use：Depression, nocturia.

(3) Market Status：■Currently available in the domestic market (License number: Wei Shu Yao Shu Zi No. 047966).

Selective serotonin reuptake inhibitor (SSRI)

The mechanism of action of the selective serotonin reuptake inhibitor (SSRI) **sertraline** is believed to be related to the inhibition of serotonin (5-HT) reuptake in the central nervous system. Clinical studies have confirmed that when humans receive appropriate doses of sertraline, it can inhibit the reuptake of serotonin into human platelets.

(1) Product Name： Lofot (Lofotidine) Film-Coated Tablets 50 mg

(2) Indications/Intended Use：Depression, obsessive-compulsive disorder (OCD), panic disorder, post-traumatic stress disorder (PTSD), social anxiety disorder, and premenstrual dysphoric disorder (PMDD).

(3) Market Status：■Currently available in the domestic market (License number: Wei Shu Yao Shu Zi No. 021780).

Proton-pump inhibitor (PPI)

Proton-pump inhibitors (PPI) work by specifically inhibiting the (H+, K+)-ATPase enzyme system located on the surface of gastric parietal cells, thereby reducing gastric acid secretion. Since this enzyme system functions as the "proton pump" within the parietal cells, blocking the final step of gastric acid production, PPIs are classified as acid pump inhibitors. They are capable of inhibiting both basal and stimulated gastric acid secretion, regardless of the stimulus. Lansoprazole does not possess anticholinergic

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or histamine H2-receptor antagonist activity.

(1) Product Name：Takepron (Lansoprazole) Orodispersible Tablets 30 mg

(2) Indications/Intended Use：Treatment of gastric ulcers, duodenal ulcers, gastroesophageal reflux disease (GERD) – erosive reflux esophagitis, symptomatic treatment of GERD. Zollinger-Ellison syndrome, in combination with antibiotics for the treatment of Helicobacter pylori-related peptic ulcers, and treatment of gastric ulcers induced by NSAIDs.

(3) Market Status：■Currently available in the domestic market (License number: Wei Shu Yao Shu Zi No. 024273).

(3) Main Inclusion and Exclusion Criteria for the Study：

The physician or relevant research personnel conducting this study will discuss the necessary criteria for participation with you. Please cooperate and honestly inform us of your past health conditions. If you do not meet the eligibility criteria for participation, you will not be able to join this study.

1. Inclusion Criteria (Eligibility for Participation in the Study)：

(1) Aged between 18 and 75 years, conscious, and willing to sign the informed consent form.

(2) Participants with chronic esophageal symptoms associated with esophagogastric dysmotility disorders (such as heartburn, acid reflux, sensation of a foreign body in the throat, difficulty swallowing, and chest pain or discomfort).

2. Exclusion Criteria (If you have any of the following conditions, you will not be able to participate in this study)：

(1) Esophageal stricture, or a history of esophageal, gastrointestinal, or throat surgery.

(2) Structural esophageal diseases (such as diverticula, esophageal rings, etc.), infectious esophagitis, erosive esophagitis, or eosinophilic esophagitis.

(3) Non-erosive reflux disease or significant esophageal motility disorders.

(4) A history or current diagnosis of malignancy in the esophagus, gastrointestinal tract, or other organs.

(5) Major endocrine or rheumatological/immune diseases that could affect gastrointestinal motility.

(6) Continuous use of medications that may impact esophageal motility (such as anticholinergics, opioids, nitrates, calcium channel blockers, etc.) in the past month.

(7) Use of or current treatment with antidepressants, selective serotonin reuptake inhibitors (SSRIs), or other psychiatric medications within the past three months.

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(8) Pregnant or breastfeeding women.

(9) Individuals with mental health disorders or those unable to cooperate.

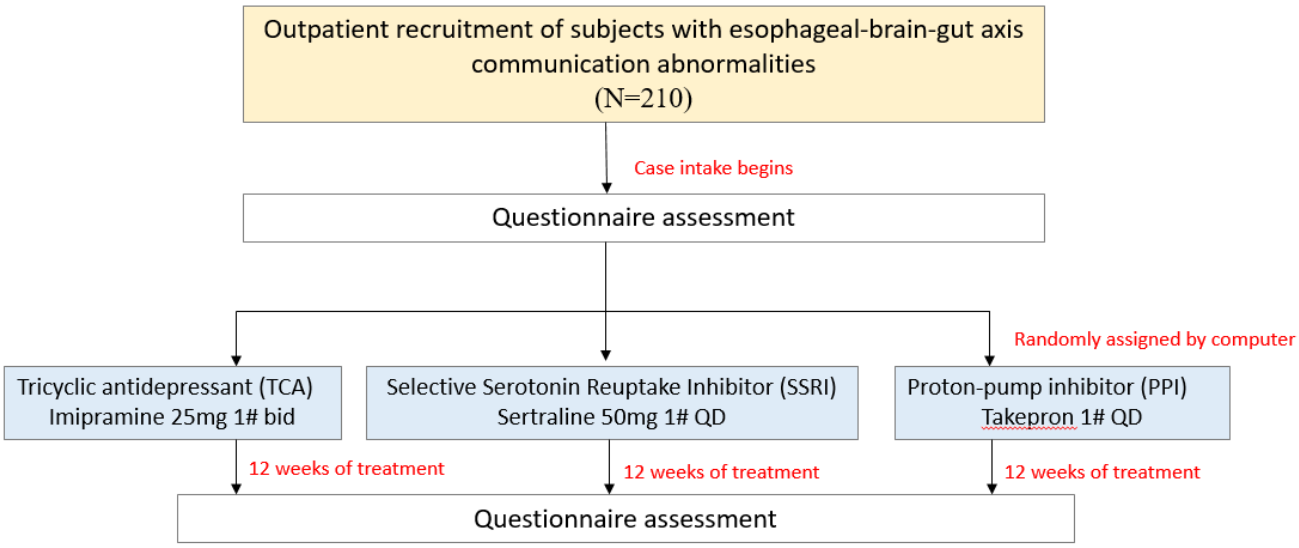
(10) Known allergy to tricyclic antidepressants.

(11) Known allergy to selective serotonin reuptake inhibitors (SSRI).

(12) Known allergy to any component of proton-pump inhibitors (PPI).

(4) Study Methods and Related Procedures：

Trial Procedure Flowchart：



Research Steps：

This study is planned to last for two years, with the research period ending on December 31, 2025. We intend to recruit participants with esophageal symptoms related to disorders of brain-gut axis communication from the gastroenterology outpatient clinic. Each participant will first complete a questionnaire that includes the Gastroesophageal Reflux Disease Questionnaire (GERDQ), PROMIS GERD, DSI & GSS, RSI, the Brief Esophageal Dysphagia Questionnaire (BEDQ), the Esophageal Hypersensitivity and Anxiety Scale (EHAS), the Visceral Sensitivity Index (VSI), and questionnaires related to sleep and mental health (such as the Pittsburgh Sleep Quality Index (PSQI), the Taiwanese Depression Questionnaire (TDQ), the State-Trait Anxiety Inventory (STAI), the Functional Dyspepsia (FD) Questionnaire, the Irritable Bowel Syndrome (IBS) Questionnaire, the Short Form Health Survey (SF-12), and the Northwest Esophageal Quality of Life (NEQOL) scale). It will take approximately 20 to 30 minutes for participants to complete these

questionnaires.

Afterward, participants will be randomly assigned by computer to one of three treatment groups for 12 weeks: (1) a tricyclic antidepressant (TCA) treatment group, (2) a selective serotonin reuptake inhibitor (SSRI) treatment group, or (3) a control group receiving proton pump inhibitor (PPI) treatment. We plan to recruit 70 participants for each group: TCA, SSRI, and PPI, with each participant having about a 1/3 chance of being assigned to one of these three groups.

In the TCA group, participants will receive 25 mg of clomipramine hydrochloride (Jianan film-coated tablets, Taiwan FDA No. 047966), taken twice daily. In the SSRI group, participants will receive 50 mg of fluvoxamine maleate (Luvox film-coated tablets, Taiwan FDA No. 021780), taken once daily. In the control group, participants will receive 30 mg of pantoprazole sodium (Takeda Pantoprazole oral dissolving tablets, Taiwan FDA No. 024273), taken once daily. After the 12 weeks of treatment, participants will complete a follow-up questionnaire, thus concluding the trial.

(5) The potential risks, their likelihood, and mitigation measures：

During the trial, the investigator and other trial staff will regularly monitor you for any side effects. If necessary, additional visits and tests will be arranged. If you experience any side effects, please inform the investigator and other trial staff. The investigator will determine the appropriate course of action based on your condition.

- Tricyclic antidepressants (such as Sinequan tablets) may cause side effects, including dizziness, drowsiness, dry mouth, and nausea.
- Selective serotonin reuptake inhibitors (such as Lustral tablets) may cause side effects, including dizziness, fatigue, excessive stomach acid, hiccups, and sexual dysfunction.
- Proton pump inhibitors (such as Teclozol orally disintegrating tablets) may cause side effects, including headache, dizziness, diarrhea, abdominal pain, constipation, and nausea.
- If the time required to complete the questionnaire causes discomfort to the participant, they can inform the principal investigator or other research staff at any time. Should the participant wish to withdraw from the study, we will respect their decision.

If you experience any of the serious or dangerous side effects mentioned above, you should promptly：

1. Call the 24-hour emergency contact number.
2. Go to the nearest emergency room if necessary.

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(6) Other alternative treatments and explanations：

Your participation is not mandatory. If you choose not to participate in the study, the doctor will monitor your symptoms through routine check-ups and provide appropriate medical treatment.

(7) Expected benefits of the trial：

The 12-week proton pump inhibitor (PPI) treatment in this trial is in line with current standard treatment and recommendations. The trial expects that the neuromodulator will improve symptoms and the impact caused by those symptoms.

(8) Contraindications, restrictions, and requirements for participants during the trial：

During your participation in this trial, please follow the guidelines below for your safety：

1. The contraindications for tricyclic antidepressants (such as Sinequan tablets) are：

(1) Co-administration with MAO inhibitors, which may lead to hyperthermia, severe convulsions, and seizures. A minimum of 14 days should be allowed between the use of these two medications.
(2) Acute myocardial infarction.
(3) Known allergy to tricyclic antidepressants.

2.The contraindications for selective serotonin reuptake inhibitors (such as Lustral tablets) are:

(1) Patients with a known allergy to this medication.
(2) Contraindicated in patients taking pimozide.
(3) Should not be used in combination with MAO inhibitors or within 14 days after discontinuing MAOI treatment. MAO inhibitors should not be used until at least 14 days after stopping Zoloft.

3. Proton pump inhibitors (such as Teclozol orally disintegrating tablets)：

should be taken once daily, before a meal. The tablet should not be chewed. Place the tablet on the tongue and allow it to dissolve. You can drink water or not, until the particles are small enough to swallow. The tablet typically dissolves in less than a minute. Patients who are known to be allergic to any component of Teclozol orally disintegrating tablets should not use this medication. Allergic reactions may include hypersensitivity reactions, anaphylactic shock, angioedema, bronchospasm, acute interstitial nephritis, and hives.

- For your safety, if you experience any discomfort, illness, adverse effects, or abnormal conditions during the trial, whether or not you believe they are related to the trial, you should inform your study doctor.
- If you have any questions, please do not hesitate to ask. Feel free to directly address them with your study staff (doctor, nurse, or assistant).

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(9) Confidentiality of Participant Personal Information：

Hualien Tzu Chi Hospital will handle any records and personal privacy information that could identify you as confidential and will not disclose it. Researchers will use a study code to represent your identity, and this code will not contain identifiable information such as your name, national ID number, or address. If the trial results are published, your identity will remain confidential.

You also understand that by signing the consent form, you agree that your original medical records may be directly reviewed by monitors, auditors, the Hualien Tzu Chi Hospital Institutional Review Board, and regulatory authorities to ensure that the clinical trial process and data comply with relevant laws and regulations. These individuals are committed to maintaining the confidentiality of your identity. Except for the institutions mentioned above, which have legal authority to review your records, we will take great care to protect your privacy.

(10) Withdrawal and Termination of the Trial:

You are free to decide whether or not to participate in this trial. You may also withdraw or discontinue your participation at any time during the trial, without providing any reason. This will not cause any discomfort or affect the medical care provided by your doctor in the future.

If important new information arises during the course of the trial (such as information that may affect your rights or influence your decision to continue participating), you will be notified and provided with further explanations. You will then have the opportunity to reconsider whether to continue, and the decision is entirely up to you. This will not cause any discomfort or affect the medical care provided by your doctor in the future.

The principal investigator may also decide to terminate the entire trial if necessary.

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(11) Damage Compensation and Insurance：

Participating in a clinical trial carries certain risks. To ensure that you may be protected in case of any adverse reactions leading to harm from participating in the trial, please carefully review the following details:

1. **Compensation for Harm:** According to the clinical trial protocol established by this research, Hualien Tzu Chi Hospital will be responsible for compensating any damages caused by adverse reactions. However, no compensation will be provided for adverse reactions that are foreseeable, as listed in this consent form.
2. **Medical Care:** If an adverse reaction or harm occurs in accordance with the clinical trial protocol, this hospital is willing to provide professional medical care and consultations. You will not be responsible for paying for the necessary medical treatment related to the adverse reaction or harm.
3. **Other Compensation:** Aside from the compensation and medical care mentioned above, no other forms of compensation will be provided by this study. If you are not willing to accept these risks, please do not participate in the trial.
4. **Legal Rights:** Signing this consent form will not cause you to forfeit any of your legal rights.
5. **Liability Insurance:** This study has not purchased human clinical trial liability insurance. If you do suffer harm due to an adverse reaction from participating in this trial, the aforementioned compensation, including reasonable medical expenses, will be provided, but only under the following conditions: You must follow the trial physician's instructions when using the experimental drug; your harm must not be intentional; and you must adhere to the medical recommendations of the trial physician.

(12) The storage, use, and reuse of the subject's specimens (including derivatives) and personal data.

Storage and Use of Personal Data

The personal data and related information you provide will be used for this research project and stored in the Gastrointestinal Function Testing Room at Hualien Tzu Chi Hospital until December 31, 2028. Upon the expiration of the retention period, the data will be legally destroyed. To protect your personal privacy, your

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name and related personal data will be replaced with a study identification number to ensure that your information remains fully confidential.

If you have any concerns regarding the use of your personal data or wish to have your data destroyed, please contact us immediately:

- Contact person: Dr. Wei-Yi Lei
- Phone: 0970-339629
- Department: Gastrointestinal Function Testing Room
- Phone: 03-8561825 ext. 13224
- Address: 707, Section 3, Zhongyang Road, Hualien City, Taiwan

You may also contact the Hualien Tzu Chi Hospital Research Ethics Committee for assistance in resolving any disputes related to the use of personal data in the study:

- Phone: 03-8561825 ext. 12124.

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(13) Participant Rights：

1. 1. If you have any questions about the nature of the study, concerns about your rights as a patient, or doubts about potential harm caused by participating in the research, you may contact the Research Ethics Committee at Hualien Tzu Chi Hospital for consultation. Phone: 03-8561825 ext. 12124.
2. 2. Any significant findings during the study that may affect your health or your willingness to continue in the clinical trial will be promptly communicated to you. If you decide to withdraw, the physician will arrange for you to continue receiving medical care. If you choose to continue participation, you may be required to sign an updated consent form.
3. 3. For the purpose of conducting the study, you will be under the care of Dr. Wei-Yi Lei. If you have any questions or concerns, either now or during the trial, please feel free to contact Dr. Wei-Yi Lei at the Gastroenterology Department of Hualien Tzu Chi Hospital. (24-hour contact number: 0970-339629).
4. 4. A compensation of 500 NTD will be provided to you for transportation and time costs upon signing the consent form and completing the first questionnaire evaluation.
5. 5. If, within 2 years after the study ends, any unanticipated findings arise that directly impact your safety, you will be notified.
6. 6. If, at the end of the study, there are significant improvements from the medication, and you are willing, the medication may be provided to you free of charge.
7. This consent form is provided in duplicate. The study investigator or authorized personnel has given you a copy of the consent form and fully explained the nature and purpose of the study. The physician has answered all your questions regarding the medication and the research.

I acknowledge receipt of a copy of the consent form.

Signature：_____ Date：_____ Year _____ Month _____ Day

(14) Potential Commercial Benefits Arising from This Study：

This study is not expected to generate any patents or other commercial benefits.

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(15) Agreement Signing Instructions：

1. The consent form should be explained to the research participant by the principal investigator or their authorized personnel, who should also address any questions the participant may have regarding the study. Afterward, the investigator or authorized personnel should sign and date the form. The research participant or their representative should then be given time to consider the information before signing the form.
2. **Timing for the signature of the legal representative/individual with consent authority/guardian/ assistant：**

   * Article 79 of the Medical Care Act / Article 12 of the Human Research Act / Article 5 of the Good Clinical Practice Guidelines for Drug Trials / Article 6 of the Guidelines for Collection of Human Biological Samples for Research / Articles 13 and 15 of the Civil Code：

   (1) If the participant is a person with no legal capacity (a minor under seven years of age or a person declared under guardianship), the legal representative shall act on their behalf; for a person declared under guardianship, the guardian shall serve as their legal representative.

   (2) If the participant is a person with limited legal capacity (a minor over seven years of age or a person with mental disorders or other cognitive impairments, such that their ability to express or recognize the effect of their expression is significantly impaired, and they have been declared under court-appointed assistance), consent must be obtained from both the individual and their legal representative or assistant.

   (3) If the participant is neither a person with no legal capacity nor a person with limited legal capacity, but due to confusion of consciousness or mental and intellectual impairments, they are unable to communicate effectively or make judgments, consent may be given by someone with the authority to do so. The individuals with consent authority include their spouse or cohabiting family members.

   (4) When the research subject is a fetus, consent must be obtained from the mother.

   (5) The provision of cadaveric specimens should be based on written consent from the participant's closest family member or the individual prior to their death.

3. **The timing for the witness signature:**

   *Good Clinical Practice (GCP) Guidelines, Article 21 / Civil Code, Article 3：

   (1) If the participant, legal representative, or person with consent authority is unable to read, a witness must be present to participate in all discussions regarding the participant's consent form. The witness should read the consent form and any other written materials provided to the participant, to witness that the study investigator or their designated personnel has thoroughly explained the contents to the participant, legal representative, or person with consent authority, and ensure that they fully understand all the information.

   (2) The participant, legal representative, or person with consent authority must still sign the consent form personally and include the date. However, a thumbprint may be used in place of a signature.

   (3) After the oral explanation has been completed and the witness is certain that the participant, legal representative, or person with consent authority has given their consent freely and voluntarily, the witness must sign the consent form and include the date.

   (4) Research personnel cannot serve as a witness.

   (5) If a thumbprint, cross, or other symbol is used instead of a signature, the document must be signed by two individuals as witnesses, and this will have the same legal effect as a signature.

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4. Explanation of the signing order for parties with consent rights：

* Article 12 of the Human Research Act: Research subjects are limited to adults with decision-making capacity, excluding fetuses or corpses. However, if the research is clearly beneficial to a specific population group or cannot be replaced by other subjects, this limitation does not apply. When the research subject is an adult under the exceptions mentioned above, consent must be obtained from their relatives in the following order:

1. Spouse.
2. Adult children.
3. Parents.
4. Siblings.
5. Grandparents.

The written consent obtained from the relatives as specified above can be provided by one person. If the relatives' opinions are inconsistent, the order should follow the above sequence. Among individuals in the same sequence, priority is given to the closest relatives by degree of kinship. If the degree of kinship is the same, priority is given to cohabiting relatives, and if there are no cohabiting relatives, priority is given to the eldest.

(16) Signature

1. The principal investigator, co-investigator, or their authorized personnel have thoroughly explained the nature and purpose of the research methods outlined in the study plan, as well as the potential risks and benefits.

Principal Investigator / Co-Investigator Signature: _____

Date: _____ Year ____ Month ____ Day

Other researchers involved in the consent process, including explanation and discussion, Signature: _____

Date: _____ Year ____ Month ____ Day

2. After the explanation, I have fully understood the research methods mentioned above, as well as the potential risks and benefits. Any questions regarding this study plan have also been thoroughly explained. I agree to participate in this research voluntarily and will keep a copy of the consent form.

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Participant's Signature: _____

Date: _____ Year ____ Month ____ Day

Date of Birth: _____ Year ____ Month ____ Day

Phone: _____

National ID Number: _____

Gender: _____

Mailing Address: _____

* **When the subject of the study meets the criteria outlined in item 2 of the [Consent Form Signing Explanation], this section must be completed with the appropriate signatures.**

Legal Guardian/Party with Consent Rights Signature: _____

Date: _____ Year ____ Month ____ Day

Relationship to Participant (Please circle): Self, Spouse, Father, Mother, Son, Daughter, Other: _____

Mailing Address: _____

Phone: _____

* **When the subject of the study meets the criteria outlined in item 3 of the [Consent Form Signing Explanation], this section must be completed with the appropriate signatures.**

Witness 1 Signature: _____

Date: _____ Year ____ Month ____ Day

Phone: _____

Witness 2 Signature: _____

Date: _____ Year ____ Month ____ Day

Phone: _____