Informed Consent Form

The text of is a writing instruction, please delete it after completing the content of the consent form. Once the consent form is completed, please print it on both sides and submit it to the IRB along with the submittal documents.
This subject consent form must be reviewed and approved by the Human Research Ethics Committee of the Hospital, and the same applies when amended. The program host or his/her designated agent should personally explain the details to the subject and ask the subject to sign after careful consideration.

Study Title: *Adherence as a Moderator of Phosphorus Education Effectiveness in Hemodialysis Patients*
IRB Number: *JMRPGJP0071*
NCT Number: *Pending*
Document Date: **July 29, 2024**

1. Plan name: *Adherence as a Moderator of Phosphorus Education Effectiveness in Hemodialysis Patients*

2. Research basic information Medical Record Number:
1.Plan No. :
IRB Case Number / Application Number：*JMRPGJP0071*
2. Experimental institutions:
3. The executor's affiliation:
4. Entrusting unit/manufacturer: Dali Renai Laboratory Medicine Department
5.Presenter : _____Service Units : _____
Job Title: _____Tel: _____
Co-Moderator: _____Service Unit: _____
Job Title:_____Industries Tel: _____
Subject's emergency contact number:
Co-host: _____Service Unit:_____
Job Title: _____Tel:_____
Subject's emergency contact number:
6. Subject Name: Subject Study Number:
Gender: Date of birth:
Address :
Contact Number :

3. Introduction:

Hello, we invite you to participate in a study on the effect of proper health education to control phosphorus ions, and nurses and medical staff will inform you of what patients with chronic kidney disease should pay attention to in diet, medication and daily life through health education. In order to determine which health education model can achieve the best results for each patient, we will currently conduct research at Dali Renai Hospital. In accordance with the regulations of the competent health authorities, you must be

informed of the purpose of the test and the purpose of the report, the test and the possible risks. Before you agree to participate in this study, the relevant medical and nursing staff will explain the contents of this subject consent form to you, please read this subject consent form thoroughly again and ask any questions clearly.

4. Objectives:

The purpose of this study is to study the effect of the module of health education content and stimulation intensity for patients with chronic kidney disease, entering the ESG2.0 era, all companies have begun to work issues such as decarbonization and environmental protection, the medical side has also begun to advocate paperless digitalization, and smart medical care has also continued to improve and join clinical medical operations. This study aims to further explore the combination of educational content and stimulation intensity, which has a significant effect on the phosphorus ion control of patients with kidney disease, so as to improve the effectiveness of health education and reduce the excess consumption of nursing capacity through scientific evidence.

In terms of patients, it can also reduce repetitive and ineffective health education cycles, thereby improving the quality of medical care and the friendly relationship between doctors and patients.

V. Inclusion and Exclusion Criteria:

[Note: If the inclusion/exclusion condition is "non-"essential", if the inclusion/exclusion condition is the medical professional judgment condition of the screening subject, it is not necessarily necessary to list it; However, if the inclusion/exclusion criteria are contraindications, or related to the patient's self-care and decision-making intentions, please list them here.

[If the recruits are employees or students of the institution, the following conditions must be met before they can be included: (1) meet the inclusion conditions of the subjects in the study; (2) The investigator or the person related to the research is not the supervisor to whom the subject directly belongs, and is not responsible for evaluating the performance; (3) When recruiting subjects, avoid individual solicitation, and recruit by open recruitment (posters or announcements) or anonymous recruitment.

1. You will be eligible to participate in this trial if you meet the following inclusion/exclusion criteria

1. Inclusion criteria

(1) Willing to sign a written consent form for the subject

(2) Male and female subjects with chronic kidney disease

(3) Ability to think and express behavior

(4) Men and women over 20 years of age

2. Exclusions

(1) Those who suffer from notifiable infectious diseases before the screening period

(2) Those who are unable to express their language clearly

6. Description of test methods and procedures:

[The number of subjects is about 150 people through the module design, and different health education content and intensity treatment are carried out, the case assignment is randomized, the health education treatment process lasts for two months, and the important matters related to the sample collection, medical record review, follow-up examination and examination or disease information are required according to the needs of each research plan, among which an additional 1cc is collected for the research in the routine heme test schedule in the third week, and the actual effect of the health education content and intensity on the case is stimulated by each module. 】

7. Expected risks, side effects, incidence and treatment methods:

[In the past, the incidence of other risks and side effects was less than 1%. 】

1. Physiological aspects:

2. Psychological aspects:

3. Social aspects: Subjects are currently unable to predict the impact on their social rights and interests caused by data leakage, such as schooling, employment, medical treatment and insurance. The project will ensure that the data of the subjects themselves and the subjects are not leaked.

8. Other possible treatment methods and explanations:

[No other treatment]

9. Contraindications and restrictions of this test, please be sure to fully cooperate with the following matters: [None]

10. Expected test effect:

[From the past data, the expected effect of the health church, through this study can have a deeper understanding of the strength and content of the health education, your participation in this trial does not guarantee that it will be effective for you, although your participation in the study will not bring direct benefits to you, but the research results may help nephrologists and medical staff to understand the condition of dialysis patients, and benefit future patients. 】

11. Handling of emergencies:

[Emergency Contact Notice: Program Host Dialysis Professional Technician Chen Weihua, Tel: 0963425288]

XII. Subsidy, Expense Burden and Compensation for Damages:

1. Subsidy:
[Subsidy for participating in the trial: Explain the nutrition expenses that the subjects can receive, and in accordance with Items 2 and 3 of Article 10 of the Guidelines for Good Clinical Trials of Drugs of the Ministry of Health and Welfare, the method, progress and amount of the subsidy shall be detailed in proportion. 】
2. Expense Burden:
[You do not have to pay anything to participate in this trial]
3. Compensation for damages: The black part of the statement of compensation for damages in the following cases shall not be arbitrarily added or modified, nor shall there be conditions that may or restrict or derogate from the rights and interests of the subjects
(1) If the clinical trial/research plan is formulated according to the institute, and the damage caused by adverse reactions occurs, the damage shall be caused by (if there is a sponsor, please fill in: **the full name of the trial commissioning manufacturer**)/(if there is no sponsor, please fill in: **this institute/the university** (the implementing agency is the two universities) **and the trial host**) [please revise the red letter statement according to the source of funding for the research] Bear the responsibility of compensation in accordance with the law. However, no compensation will be made for the predictable adverse reactions recorded in this subject's consent form.
(2) In the event of adverse reactions or damages in accordance with the clinical trial/research plan of the Institute, the Hospital/University is willing to provide professional medical care and medical consultation in accordance with the discretion of the implementing agency. You will not be responsible for the necessary medical expenses for the treatment of adverse reactions or injuries.
(3) Except for the first two types of compensation and medical care, this study does not provide other forms of compensation. If you are not willing to accept this risk, please do not participate in the trial/study.
(4) You will not lose any legal rights by signing this consent form.

13. Protection of privacy and confidentiality:

1. There will be a research code representing your identity, and this code will not show your name, ID number, or address.

2. The results and diagnosis of your visit will be kept confidential and your privacy will be carefully maintained. If hair

Table the results of the study, and your identity will remain confidential.

3. Please also understand that if you sign the consent form, you agree that your visit records can be directly monitored by the monitor, auditor and research ethics committee

The Committee and the competent authority will review the research process and data to ensure that the research process and data comply with the

relevant legal and regulatory requirements. The above-mentioned people We also undertake not to breach the confidentiality of your identity.

4. Please understand that due to safety considerations, the research team may inform or contact your attending physician in other specialties to let them know about the trials and disease treatment status you are participating in, so as to avoid harm caused by drug interactions.

14. Withdrawal and Termination of Trial:

The subject or consenting person has the right to terminate the trial at any time without giving any reason, and this will not detract from your legitimate medical rights and legal rights. The trial host or sponsor may also suspend the trial if necessary.

For your safety, you must withdraw from the trial/study when:

(Please list the conditions for withdrawal)

When there is important new information in the conduct of the trial/study (meaning that it is related to your interests or affects your willingness to continue to participate), you will be notified and further explained, and you are asked to reconsider whether to continue to participate, and you are free to decide that it will not cause any unpleasantness or affect the future medical care of your doctor.

When you withdraw from the trial/study or the host determines that you are not suitable to continue participating in the trial/study, the data obtained before the withdrawal will be retained and will not be removed. After opting out, you will be able to choose what to do with the specimen you have previously provided and decide whether or not to consent to the trial host (or sponsor) continuing to collect your data.

1. For the specimen I previously provided

□I agree to continue to authorize this trial/study to be used in studies related to the disease of this trial. If the scope of use is beyond the scope of the original written consent, I will need to obtain my consent again.

□ do not agree to continue to authorize the use of this test/study, but in order to ensure the accuracy of the completed examination, it is agreed that the relevant specimens of the test/study can be reconfirmed by the laboratory and destroyed.

□ do not agree to continue to authorize the use of this trial/study, please destroy my previous samples related to this trial/study from the date of withdrawal.

2. After the withdrawal, let the trial host (or sponsor) continue to collect my information, such as obtaining follow-up medical procedures and laboratory test results through my medical records. Your privacy and the confidentiality of your personal data will be maintained while the data is collected.

□ consent to collection.

□ do not agree to the continued collection or review of my data in this

trial/study, except for records that can be searched through public databases.

XV. Subject's Rights:

1. For the collection, processing and use of your personal information, the test institution/trial host will handle it in accordance with the subject consent form, the relevant laws and regulations of the clinical trial and the relevant provisions of the Personal Data Protection Law. In accordance with the provisions of the Personal Data Protection Act, you can exercise the following rights by contacting the test institute/trial host in writing:
   (1) Inquire about or request access to your personal information;
   (2) request a photocopy of your personal data;
   (3) request supplementation or correction of your personal data;
   (4) request to stop the collection, processing or use of your personal data;
   (5) Request deletion of your personal data.
2. During the course of the study, any major findings that may affect your willingness to continue to undergo clinical trials will be provided to you in a timely manner. If you have any questions or conditions during the study, please contact the moderator.
3. If you have any opinions about your rights as a subject or suspect that you have been harmed by your participation in the research, you can contact the Human Research Ethics Committee of Dali Renai Hospital at the telephone number of (04) 24819900 ext. 11160 or the Subject Protection Office (Tel: _____) of the institution for consultation or appeal.

16. Attribution of test results and rights and interests: [Please indicate the possible commercial benefits of the research.] If the client is not the client, it should be recorded in accordance with the content of the research commission. If the results of this pilot project generate academic literature publication, substantial benefits or other rights and interests, it is also agreed to donate to the hospital free of charge for public welfare purposes such as disease prevention, diagnosis and treatment.

Example 1:

The information obtained from this trial/study may lead to the discovery, invention or development of a commercial product, all of which belong to the commissioner of the trial. You and your family will not receive any financial benefit or monetary compensation for the research and development, invention or other discovery contained in such information, or will have ownership of the results of said invention.

Example 2:

The information obtained from this trial/study may lead to the discovery, invention or development of a commercial product. You and your family may receive any financial benefit or monetary compensation for the research and development, invention or other discovery contained in such information, or have ownership of the results of said invention.

Example 3: No patent rights or other commercial benefits are expected to arise from this study.

17. Preservation and reuse of personal data, specimens and specimen derivatives:
[If this case is a manufacturer-sponsored case: if there are any remaining samples after the study, please provide an option for the subjects to choose whether to destroy or keep them for a period of time, if the subjects agree to keep them for a period of time, please indicate the storage location, storage reason, storage period, and subsequent use scope of the remaining samples]
[If this case is a non-manufacturer-initiated case: if there are any remaining samples after the end of the study, please indicate whether they are directly destroyed or need to be saved, and if they need to be saved, please provide the following three options for the subject to choose]
(If it is directly destroyed, please indicate: **after the end of this study, if there are any remaining samples, they will be destroyed uniformly and will not be saved**).
All new research proposals will be reviewed and approved by the Human Research Ethics Committee of Mahkota Hospital, and if the Human Research Ethics Committee determines that the new research is beyond the scope of your consent, we will be asked to obtain your consent again.
Whether to agree to the remaining specimens for future research purposes, and authorize the Human Research Ethics Committee of Mahkota Medical Foundation to consider whether it is necessary to obtain your consent again:

☐ 1. If you do not agree to keep my remaining samples, please destroy them after the test

Subject Signature: _____ Date: ___year___ month___ day

☐ 2. I agree to keep my remaining samples in a non-delinking manner, and if the original consent is exceeded, I will need to obtain my consent again before I can use my samples for new studies

☐I agree that the remaining samples after the completion of this study will be stored in the Human Biology Database of Mahkota Medical Foundation in Dali Renai Hospital for use in other subsequent studies approved by the Human Research Ethics Committee of this hospital. (Please also sign the Human Biodatabase Participant Consent Form)

Subject Signature: _____ Date: year month day

☐I agree that the remaining samples after the completion of this study will be deposited into the Mahkota Medical Foundation Organizational Bank of Mahkota Hospital for use in other subsequent studies approved by the Human Trial Ethics Committee of this hospital. (Please also sign the consent form for the remaining specimens)

Subject Signature: _____Date: year month day

3. Genetic test results (if genetic testing is not involved in this plan, please delete this item)

Please fill in one of the following items according to the test status

Example 1: If there is any new information about the genetic test results, do you need to provide information to let them know:

☐ need to be informed ☐ don't need to be told

Example 2: Genetic test results do not inform individual patients.

XVIII. Declaration:

1. The content of this test and the consent form have been completely verbally informed and explained (please fill in the name of the person who obtained the consent form), and the subject/legal representative has fully understood and agreed to this consent form in duplicate, and a copy of the consent form for the physical examination of the research employer has been handed over to the subject.

2. If you participate in this study as a prisoner, there will be no impact on your parole. [When your study includes subjects with inmates, please add note 2., if the study is not related to the inmates, please delete note 2.]

A.Subjects : ___(Block name)

(signature) Date: year month day

B.Consentee: ___(Block name)

(signature) Date: year month day

C.common/Co-hosts: ___(Block name)

(signature) Date: year month day

D.Study Host: __(Block name)

(signature) Date: year month day

**This field must be signed when the recipient meets item (1) of the [Instructions for Signing the Consent Form].

And.legal representative/There is a person who has the right to consent/guardian/Helpers:

(Block name)

(signature) Date: year month day

Relationship with Subject:

When the subject of the case meets the requirements of item (2) of the [Instructions for Signing the Consent Form], this field must be signed

F.Witness: _(Block name)

(signature) Date: year month day

【Instructions for Signing the Consent Form】

(1) Timing of use by legal representatives/persons with the right of consent/guardians/assistants:

*Article 79 of the Medical Care Act / Article 12 of the Human Research Act / Article 5 of the Guidelines for Good Clinical Trials of Drugs:

1. The subject is incapacitated (a minor under the age of seven or a person who has been declared under guardianship), and the legal representative shall act as the subject; For persons who have been declared guardian, the guardian is to serve as their legally-designated representative.
2. If the subject is a person with limited capacity (a minor over 7 years old or a person who has been declared by assistance), the consent of the subject and his/her legal representative or assistant person shall be obtained.
3. If the subject is not incapacitated or has limited capacity, but is unable to communicate and judge effectively due to confusion or mental and intellectual disabilities, the person with the right to consent shall do so.

(2) Timing of the use of witnesses:

*Article 21 of the Guidelines for Good Clinical Trials of Drugs:

1. If the subject, the legal representative, or the person with the right to consent is unable to read it, the witness shall be present to participate in all discussions about the consent form. The witness should read the subject's consent form and provide any other written information of the subject to witness that the study host or his/her designated person has accurately explained its contents to the subject, legal representative or person with the right to consent, and to ensure that he or she fully understands the contents of all the information.
2. The subject, legal representative or person with the right of consent should still sign and date the consent form of the subject. However, a fingerprint can be used in lieu of a signature.
3. After completing the oral description and confirming that the consent of the subject, the legal representative or the person with the right to consent is entirely of his or her free will, the witness shall sign and date the consent form of the subject.
4. Persons related to the research must not be witnesses.

(3) The order of signature by the legal representative:

*According to Article 79 of the Medical Care Act, medical institutions shall exercise necessary medical care when conducting human trials, and shall first obtain the written consent of the person being tested; The subjects of the test were limited to adults with interesting abilities. However, this restriction does not apply to trials that are clearly beneficial to the health rights and interests of patients suffering from specific population groups or special diseases.

*According to Article 5 of the Measures for the Administration of Human Experiments: For adult or married minor subjects recruited by proviso in accordance with Paragraph 1 of Article 79 of the Medical Treatment Law, the host shall obtain the consent of at least one of their related persons in the following order:

1. Spouse.
2. Parents.
(3) Adult children living together.
四、Grandparents living with the participant.
五、Siblings living with the participant.
6. Other relatives who have lived together in the last year. The consent of the persons involved in paragraphs 1 to 5 of the preceding paragraph shall take precedence over those who have cohabitation.

The consent of the person concerned in the first paragraph shall not be contrary to the intention expressed by the subject.

【Mahkota Medical Foundation Osato Mahkota Hospital Study Participants' Notice】

Dear subjects, family members, and the public,

In order to ensure the safety and rights of your participation in the research, the following will explain to you the efforts and checks made by the Human Research Ethics Committee of Mahkota Hospital, including how the research plan is reviewed, what is the focus of the review, and the rights of the subjects.

What is Research?

"Research" and "treatment" are not the same. "Treatment" refers to a research process that has been carried out to fully understand the possible outcomes and the incidence of side effects after treatment. But research is about answering questions that we didn't know before, and it's not entirely clear what the results will be. Therefore, participation in the study is not mandatory, and failure to participate will not affect your right to receive subsequent medical care or suffer any unfair treatment.

What is a Human Research Ethics Committee?

The Institutional Review Board (IRB) is a review body established to ensure that human trials or research are scientifically and ethically appropriate. It is composed of medical professionals with professional knowledge, as well as non-medical backgrounds such as legal experts, social justice figures or representatives of civil society organizations, to help researchers understand the situation of subjects and ensure their safety and rights. If you have any questions about your rights and interests in participating in the study, you can ask the Human Research Ethics Committee of Mahkota Hospital.

How does the Human Research Ethics Committee review clinical trials/research proposals? What are the main points of the review?

(1) Research conducted at Mahkota Metropolitan Hospital Osato shall be reviewed and approved by the Human Research Ethics Committee of Benevolence Hospital.

(2) The research plan submitted to the Human Research Ethics Committee will be reviewed by the committee members or experts in an independent, professional and cautious manner, and the key points of the review include: whether the subjects are informed in detail about matters related to the trial (including: the purpose of the trial, the procedure for conducting the trial, etc.), other possible alternative treatment methods, the side effects, risks and benefits of participating in the study, how to withdraw from the study, and whether the care and privacy of the participants are protected.

(3) What are the possible risks to the investigators of these research plans when conducting a clinical study review, which will be evaluated by the Human Research Ethics Committee of Mahkota Otto Hospital. Some of the risks are physical pain and discomfort, some are psychological, and some are even socially and financially impactful, and the Human Research Ethics Committee is committed to ensuring that the harm caused by these risks is minimized. In addition to the risks, we also assess the benefits that participants can expect from the study, whether the study may cure the disease, may not cure the disease but may improve the quality of life of the participants, or may not be beneficial to the people who participate, but will contribute to the advancement of medical research or the discovery of new

treatments for people with the same disease in the future. The Human Research Ethics Committee of Mahniko Medical Foundation Osato Benevolence Hospital will comprehensively evaluate whether the risks of each research plan are reasonable relative to the benefits obtained, and decide whether to approve the plan.

(4) After the approval of the research plan, the Human Research Ethics Committee and the executive agency of Mahkota Otto Osato Medical Foundation will continue to supervise the approved plan to ensure that the research team properly implements the approved plan and checks the rights and interests of the subjects.

What are your rights as a subject?

Right to know

(1) What is the purpose of the study? The researcher should tell you what the purpose of the study is in plain language.

(2) What will happen during the research process?

That is, you need to know how the research process works, including: What does the research process require you to do? How to cooperate? (For example.)

How often do I need to return to my appointment? How much blood will be drawn each time? What checks to do? How much inconvenience will it bring to life?

(3) Are there any other treatments for not participating in the study?

You don't have to participate in a study, so you have the right to know if there are other treatments.

(4) What adverse reactions or risks may occur?

There are always risks associated with any study, so it is important to know how dangerous it is to participate in this study. It's also important to know what to do in the event of a danger or emergency. Who to contact? How to get in touch? And who will provide follow-up medical care? There is also the issue of associated costs. Researchers should explain this to you carefully before joining a study.

(5) What are the possible benefits of participating in the study and the expected outcomes of the trial? It is the researcher's obligation to explain to you the benefits that this research may bring to you, or that the research may not directly benefit you, but that the research results may identify new treatments that contribute to medical progress and the future of humanity in order to inform your consideration of joining this study.

(6) How do you propose if you want to withdraw from the research program? Researchers should tell you who you should contact if you want to quit after participating in a study? Is there a care plan after exiting? After withdrawing from the study, will the data you provided during your participation continue to be analyzed or saved?

(7) When you have any concerns, you can always ask the researcher about your right to freely choose to participate in the study After the researcher has fully explained to you the purpose of the study, the procedure for conducting the study, other possible alternative treatments, the possible risks and benefits of participating in the study, the expected

outcomes of the study, the procedure for withdrawing from the trial plan, and the care plan after withdrawal, you will be considered to have officially joined the study and become a subject after you have considered whether to participate in the study and signed the subject consent form.

In addition, if you wish to withdraw from the study, you can do so at any point in time and without any reason to the person involved in the study. And you

The decision to withdraw will not affect your right to receive medical care or any unfair treatment.

Protected rights

(1) Protection of privacy and confidentiality The research team is obliged to maintain your privacy for any information you provide during your participation in the research, and if the research results are published, or to ensure that the research process and data comply with relevant laws and regulations, the human research ethics committee or the competent authority (e.g., the Ministry of Health and Welfare) will review the relevant information of the research, but your identity will still be kept confidential.

(2) Retain the legal rights you now have　Participating in a clinical study does not waive any of your legal rights.