Participant Information Sheet and Consent Form

You are being invited to take part in this clinical study. This study has been reviewed and approved by the Institutional Review Board of Seoul National University Hospital, which is responsible for protecting the rights and welfare of research participants. We would now like to provide you with information about the purpose of this study, as well as your rights and responsibilities as a participant.

Before agreeing to take part in the study, you should carefully read and fully understand the contents of this document. This information sheet includes detailed explanations of the study's purpose, procedures, potential benefits and risks, and other important considerations. It also describes your right to make your own decision and to withdraw from the study at any time.

Please read this document carefully. If you have any questions or concerns, you are encouraged to ask the study doctor or research staff at any time. You should sign the consent form only after you fully understand all of the information described below and have received satisfactory answers to all your questions. Your participation in this study is entirely voluntary, and you may decline or withdraw at any time without any penalty or loss of benefits to which you are otherwise entitled.

1. Background and Purpose of the Study

Palliative care is an approach aimed at improving the quality of life of patients and their families who are facing problems associated with life-threatening illnesses. Recent studies have shown that providing palliative care early in the course of chronic serious illnesses, such as cancer, alongside disease-directed treatment can enhance quality of life and support appropriate use of healthcare services. Patients with acute critical illness admitted to the intensive care unit (ICU) experience rapidly changing medical conditions and face significant uncertainty in terms of prognosis, including potential recovery or disability. In many cases, patients are unable to make decisions for themselves, leaving their families to make urgent and complex medical decisions on their behalf, often under significant emotional distress. These circumstances make it difficult to reflect the patient's own wishes in decision-making, and can impose a psychological burden on families, sometimes leading to conflict among family members or between families and healthcare providers.

While the importance of providing palliative care to critically ill patients and their families in the ICU is increasingly recognized, little is known about the feasibility and impact of implementing consultation-based palliative care services in this setting to improve the quality of palliative care delivery. This study is a pilot investigation designed to explore the feasibility of delivering high-quality, consultation-based palliative care to patients with acute critical illness in the ICU and their families.

2. Number of Participants and Duration of Participation

This study will involve patients with acute critical illness and their family members who meet the inclusion and exclusion criteria. A total of approximately 20 critically ill patients and 20 family caregivers will be enrolled at Seoul National University Hospital.

The study will be conducted from the date of IRB approval until December 31, 2025. If you agree to participate, your participation will last from the time of enrollment until the end of follow-up. You may withdraw from the study at any time without any penalty or loss of benefits.

3. Voluntary Participation and Right to Withdraw

Participation in this study is entirely voluntary. If you decide to take part, you are free to withdraw at any time. Choosing not to participate, or deciding to withdraw from the study later, will not affect your usual medical care in any way.

Even if you initially agree to participate, you may revoke your consent at any point without facing any disadvantage or discrimination. Please note that by signing this consent form or agreeing to participate, you are not waiving any of your legal rights.

If you decide to withdraw from the study, you may inform the study doctor or research staff either

verbally or in writing. Once you withdraw, no further data will be collected, and you will no longer be contacted for research purposes. However, any data already collected prior to your withdrawal may still be used for the study.

4. Study Procedures and Assessments

This study is a single-arm interventional study, and all participants will receive the intervention. Before any study-related procedures begin, you will be asked to listen to an explanation of the study's purpose and procedures, read this consent form, and sign it if you agree to participate.

The study consists of two main components: the intervention and evaluation. The intervention includes four components: (1) family counseling, (2) consultation with the ICU team, (3) support for family meetings, and (4) provision of palliative care by the primary physician. Evaluations will be conducted at baseline and during two follow-up periods.

Intervention

1) Family Counseling

An appointment will be scheduled for a counseling session with a social worker from the palliative care consultation team. This will take place in a private space within the hospital. The aim of this session is to help support future medical decision-making in the best interests of the patient in the ICU. The social worker will explore the family's understanding of the patient's condition, the patient's values and preferences, the care or treatments the family wishes to prioritize, and any challenges the family may be facing.

The session will last approximately one hour, and the conversation will be audio-recorded and later transcribed for analysis.

2) Provision of Consultation

Based on an assessment of the family's psychosocial needs, decision-making challenges, and the patient's medical condition, the palliative care consultation team will provide recommendations to the ICU medical team. This process supports the integration of holistic palliative care into the ICU treatment plan.

Consultation content may include pain and symptom management, understanding of the illness and decision-making conflicts, emotional and practical support for the patient and family, assistance with setting care goals based on patient values and preferences, provision of support resources, and bereavement care.

When a family meeting is recommended, an intermediate consultation may be provided to explain the rationale and help plan for the meeting, including discussion topics.

3) Support for Family Meetings

Family meetings will be arranged as part of the ICU physician's palliative care strategy when needed. These meetings are held when medical uncertainty exists, when key information is lacking, when values conflict in decision-making, or when communication challenges arise between the family and healthcare providers.

Depending on the purpose and nature of the meeting, a physician or social worker from the palliative care consultation team may facilitate the meeting. Each session is expected to last approximately one hour and will be audio-recorded.

4) Provision of Palliative Care by the Primary Physician

The primary physician will adjust the treatment plan based on the recommendations from the palliative care consultation team and the goals of care discussed. The physician will also address the patient's and family's psychological and spiritual needs and provide appropriate support.

Documentation of these care goals will be shared among the medical team to ensure continuity, even if the care setting changes. Since care goals may evolve based on the patient's condition or the family's psychological state, regular reassessment and further discussions may be needed.

Assessments

Among the participants in this study, family caregivers will be asked to complete one questionnaire

before the intervention and two follow-up assessments: one within one week after the final consultation and another one month after the final consultation. Additionally, a one-on-one interview will be conducted at the one-month follow-up point.

There will be no questionnaires or interviews conducted directly with patients. Patient information will be collected through a review of medical records.

1) Baseline Assessment

If you decide to participate in this study, you will be asked to sign the consent form, after which the research staff will provide the baseline questionnaire.

This questionnaire is to be completed by the family caregiver and includes the following topics: demographic information of the patient and family caregiver, decision-making preferences, decisional conflict, decision-making self-efficacy, and emotional status of the family caregiver.

It is a self-administered questionnaire. You are encouraged to read each item carefully and respond to all questions. The questionnaire consists of 1 to 8 pages and is expected to take approximately 20 minutes to complete.

2) Follow-Up Assessments

There will be two follow-up assessments, both conducted by the family caregiver:

- Within 1 week after the final consultation (Questionnaire)

This questionnaire includes items related to decisional conflict, decision-making self-efficacy, decision regret, patient- and family-centered care, emotional status of the family caregiver, and satisfaction with the intervention services.

As with the baseline assessment, this is a self-administered questionnaire. It consists of 1 to 9 pages and is expected to take approximately 25 minutes to complete.

- One month after the final consultation (Questionnaire and Interview)

This assessment includes a self-administered questionnaire that focuses on decision regret, patient- and family-centered care, and the family caregiver's emotional well-being. The questionnaire consists of 1 to 5 pages and is expected to take about 15 minutes to complete.

Additionally, a semi-structured one-on-one interview will be conducted at this time to explore the family caregiver's perception of the applicability of palliative care consultation services.

If the patient has passed away by this point, the questionnaire and interview will be conducted within three months of the final consultation, taking into account the caregiver's emotional and psychological state. The interview will be audio-recorded and later transcribed for analysis.

5. Responsibilities of Study Participants

Participants in this study are expected to respond to all questions sincerely and accurately, without providing any false information.

6. Anticipated Side Effects, Risks, and Discomforts

Patients and family caregivers receiving the intervention in this study will continue to receive the standard care typically provided in the intensive care unit (including medical treatment and nursing care). In addition, they will receive counseling, education, and palliative care consultation services as part of routine clinical care. Therefore, no specific risks or adverse effects related to participation in the study are anticipated.

7. Financial Burden and Compensation for Patients and Families

There is no participation fee required to take part in this study. Any medical expenses related to clinical procedures during the study will be the responsibility of the participant and will be charged according to standard clinical practice and national health insurance regulations.

Since there will be no additional hospital visits beyond the usual care procedures during the intervention period, no transportation costs will be reimbursed for this period.

However, the family caregiver will receive a small token of appreciation (valued at 10,000 KRW) for completing each questionnaire. A total of 30,000 KRW will be provided if all three questionnaires are

completed.

Additionally, if the family caregiver participates in the one-on-one interview conducted during the final follow-up, transportation costs will be reimbursed (actual costs up to a maximum of 50,000 KRW, regardless of place of residence) due to the extra hospital visit.

These compensations will be provided based on each completed assessment, regardless of whether the participant completes the entire study.

8. Anticipated Benefits

There are no direct benefits to you from participating in this study. However, the information obtained through this study may serve as foundational evidence to support the integration of consultation-based palliative care services into routine care for critically ill patients in the intensive care unit (ICU), a population for whom such services are not yet well-established in Korea. The findings may help determine the feasibility and effectiveness of delivering high-quality palliative care to patients and their family caregivers as part of standard ICU care.

9. Ongoing Provision of New Information

If any new information becomes available during the study that may affect your willingness to continue participation, you or your legal representative will be promptly informed.

10. Withdrawal from the Clinical Trial

Your participation in this study is entirely voluntary. You may choose to withdraw from the study at any time by contacting the investigator, without any penalty or loss of benefits to which you are otherwise entitled. If you decide to discontinue your participation, please inform your physician or the study personnel to ensure that the withdrawal process is carried out safely. If you choose to withdraw from the study, you may also decide whether or not your data can continue to be used for research purposes after your withdrawal. Your decision in this regard will be respected and may contribute to the overall objectives of the study. If you decide to stop the intervention but continue with the research participation, the physician or study staff will explain which procedures will continue and what types of data will still be collected. You may be withdrawn from the study at any time for reasons including, but not limited to, the following:

Criteria for Withdrawal or Discontinuation of the Clinical Trial

(1) Criteria for Early Termination: The clinical trial will be terminated in the following cases:

① The participant (patient or family caregiver) withdraws their consent to participate in the study.

② The participant (patient or family caregiver) no longer wishes to receive further interventions.

③ The patient is discharged before the final consultation (includes both discharge due to death and survival).

④ The family caregiver passes away before the final consultation.

⑤ The investigator determines that discontinuing participation is in the best interest of the participant.

⑥ The participant fails to cooperate with the principal investigator or does not follow the investigator's instructions.

⑦ The regulatory authorities or the ethics committee/clinical research review board discontinues the study.

(2) Early Termination Procedures and Follow-up for Withdrawn Participants

Once participation is discontinued, no further interventions will be carried out, and the investigator will record the endpoint in the Case Report Form (CRF). If the participant withdraws consent, the investigator will determine whether previously collected data can still be used for research purposes. If consent is not given, any collected data will not be used, and the study records, including the withdrawal, will be stored for at least 3 years from the completion of the study and then destroyed.

For participants who discontinue the trial, with the exception of those who withdraw consent, mandatory medical record reviews will be conducted for the remaining follow-up period, but no further survey evaluations will be conducted. For those who withdraw their consent (criterion ①), the investigator will check whether previously collected data can still be used. If consent is not granted, the collected data will be discarded. In cases where the participant decides not to proceed with further interventions (criterion ②), any post-consultation surveys (post-1) or interviews (post-2) will only be administered to those who consent to participate. Additional medical record investigations will also proceed only for those who agree to continue.

11. Compensation and Treatment Measures for Harm

Patients and family caregivers participating in this study will receive interventions consisting of education and counseling. Therefore, it is anticipated that there will be no physical, mental, or specific injuries caused by participation in this study. However, if any unforeseen psychological or mental harm arises as a result of the additional procedures and interventions related to this clinical trial, apart from the standard medical care, the research team will take appropriate actions to ensure that the participant receives the necessary treatment. Since clinical information will be collected only through medical records without direct intervention with the patient, no harm is anticipated from the research.

12. Collection and Use of Personal and Sensitive Information and Consent for Disclosure to Third Parties

All information provided for this study will be strictly confidential and protected. If you agree to participate in this study, the collected data will be anonymized and may be submitted to relevant institutions. Monitors, auditors, committee members, and government authorities may access the records to verify the procedures and data integrity of the study without violating confidentiality.

The research physician and study staff will collect and use your personal information, including demographic details (e.g., gender, age), personally identifiable information (e.g., name, registration number, contact details, address), and sensitive information (e.g., socioeconomic data—income, marital status, disease status, treatment history). The records, results, and consent forms will be retained for three years, and you have the right to request the disposal of your records. The confidentiality of personally identifiable information will be strictly maintained, and health information will be provided anonymously, ensuring that the identity and location of participants cannot be discerned. Even if the study results are published, the participants' personal information will remain confidential.

During the family counseling, family meetings, and 1:1 interviews conducted as part of the study, the subjective experiences of patients and families are valuable data. Therefore, these sessions will be recorded and transcribed. Any personally identifiable information (e.g., name, birth date, address, contact details) will be anonymized to prevent identification. These materials will only be used for research purposes and will be securely stored on password-protected personal computers accessible only to the researcher. The data will be destroyed in compliance with retention policies.

The personal and sensitive information collected for this study may be used for secondary purposes outside of this study, depending on your consent. In such cases, your personal (sensitive) information will be anonymized before being used for secondary purposes. You will be asked to indicate whether you agree to the secondary use of your information. You have the right to refuse consent for the secondary use of your personal data without any disadvantage, and you may withdraw your consent at any time, even after agreeing to participate in the primary study.

13. Confidentiality of Personal Information and Records

The records collected during your participation in this study will be kept confidential. Even when the results of the study are reported, published, or presented, your personal information will remain confidential. Individuals monitoring or auditing this study, the Institutional Review Board (IRB), and relevant government authorities are allowed to access the records and personally identifiable information of participants in accordance with the relevant laws and regulations, in order to verify the study procedures and the reliability of the data. By signing this consent form, you or your legal

representative consent to the direct review of these materials.

14. Additional Information

This study has been reviewed and approved by the Seoul National University Hospital Institutional Review Board (IRB). This committee is an organization established to protect the safety of clinical research participants. If any new, significant information that could potentially affect your participation in the study is obtained, you or your representative will be informed as soon as possible. You will have the option to decide whether to continue or discontinue your participation based on this information.

If you would like to obtain additional information about the study or if any issues arise during the study, please contact the provided number.

If you have read all the information above, please ask the research staff (researcher) any questions and decide whether to participate.

If you decide to participate in the study, please sign the following form (consent form) to confirm that you have understood all the information about this study. Afterward, a copy of this form will be provided to you. Please keep the “Participant Information and Consent Form (Copy)” for your records.

Consent Form: For Patients

1. I have received an oral explanation of the study and have read the above study information. I have had sufficient discussions with the research staff about this study.
2. I have been informed of the risks and benefits of the study, and I have received satisfactory answers to my questions.
3. I voluntarily consent to participate in this study.
4. I understand that I can refuse to participate in the study or withdraw from the study at any time without affecting my future treatment, and I acknowledge that such a decision will not cause me any harm.
5. I understand that if I need to receive other treatment, fail to follow the study protocol, experience harm related to the study, or for any other reason, my participation in the study may be discontinued without my consent.
6. By signing this consent form, I agree that my personal information may be collected and processed by the researcher for medical research purposes, in accordance with current laws and regulations.
7. My signature indicates that I have received a copy of this explanation and consent form, and I understand that I can keep the copy. I have recorded my name, signature, and the date by hand.

I agree to participate in this study of my own free will.	□ **Yes** □ **No**

8. (Optional) I consent to the use of my personal (sensitive) information for secondary purposes beyond the scope of this study, and I understand the procedures for collecting and utilizing personal (sensitive) information.

(Optional) I voluntarily consent to the collection and use of my personal (sensitive) information for secondary purposes related to this study.	□ **Yes** □ **No**

Research Participant's Name	Signature	Date (YYYY/MM/DD)
Legal Representative's Name	Signature	Date (YYYY/MM/DD)
(Relationship to the Participant)		

<For Investigator Use Only>

✓ I confirm that I have provided the person named above with sufficient and thorough explanation about this study, and to the best of my knowledge, the individual clearly understands the nature, risks, and benefits of participating in this study.

✓ I confirm that I have given the individual the opportunity to ask questions about this study and have answered all questions accurately and to the best of my ability.

✓ I confirm that the individual was not coerced into signing the consent form and has agreed to participate freely and voluntarily.

✓ I confirm that I have provided the individual with a copy of the study explanation and consent form.

Investigator/Researcher's Name	Signature	Date (YYYY/MM/DD)

Consent Form: For Family caregiver

1. I have received a verbal explanation about the study, read the above information sheet, and had sufficient discussion with the responsible researcher regarding the study.
2. I have been informed about the risks and benefits of participating in this study and have received satisfactory answers to my questions.
3. I voluntarily agree to participate in this study.
4. I understand that I may refuse to participate or withdraw from the study at any time without affecting my future treatment, and that such a decision will not result in any disadvantage to me.
5. I understand that my participation in the study may be discontinued without my consent if I need to receive other treatments, if I do not follow the study protocol, if I experience harm related to the study, or for other reasons.
6. By signing this consent form, I agree that my personal information may be collected and processed by the researcher for medical research purposes within the scope permitted by applicable laws and regulations.
7. My signature indicates that I have received a copy of the information sheet and consent form and understand that I may keep this copy. I have personally written my full name, signature, and date.

I voluntarily agree to participate in this study.	□ **Yes** □ **No**

8. (Optional) I understand that, if I agree, my personal (sensitive) information may be used for secondary purposes beyond this study, and I understand the procedures for the collection and use of such information.

(Optional) I voluntarily agree to the collection and use of my personal (sensitive) information for secondary purposes beyond this study.	□ **Yes** □ **No**

Legally Authorized Representative's Name	Signature	Date (YYYY/MM/DD)

<For Investigator Use Only>

✓ I confirm that I have provided the person named above with sufficient and thorough explanation about this study, and to the best of my knowledge, the individual clearly understands the nature, risks, and benefits of participating in this study.

✓ I confirm that I have given the individual the opportunity to ask questions about this study and have answered all questions accurately and to the best of my ability.

✓ I confirm that the individual was not coerced into signing the consent form and has agreed to participate freely and voluntarily.

✓ I confirm that I have provided the individual with a copy of the study explanation and consent form.

Investigator/Researcher's Name	Signature	Date (YYYY/MM/DD)