Informed consent form

I am, Oryza Gryagus Prabu, MD., from Faculty of Medicine Universitas Indonesia will conduct a study entitled **"N-Acetylcysteine Role on Urinary KIM-1 and Serum Creatinine Level in Cancer Patient With Cisplatin Based Chemotherapy".**

I will give you information about this study and invite you to participate in this study. If you are willing to participate, you can sign this informed consent form that states that you agree to participate. Even if you agree to participate now, you are allowed to change your mind and withdraw from this study at any time in the future. You have a right to get the latest information from us about the treatment being studied in this research. If you refuse to participate or choose to withdraw from this study, that decision will not influence your relationship with me and certainly will not affect the service you will get from this hospital.

If there is any question or statement that you do not understand in this form, you can ask me for an explanation.

1. **Purpose of the study**

   This study aims to find out whether giving the medicine N-acetylcysteine (NAC) can help protect kidney health in cancer patients who are receiving chemotherapy that includes cisplatin.

2. **Participation in the study**

   The study will take place over about 8 months.

   If you decide to join, you will be asked to follow the study schedule. This includes attending interviews, medical check-ups, blood and urine tests, and taking study medication.Each interview or check-up will take about 3**0–60 minutes.**Blood and urine samples will be collected three times:

   - Before starting chemotherapy
   - One week after chemotherapy
   - Three weeks after chemotherapy

Each sampling will take about 15–30 minutes. You will be asked to take study tablets twice a day for 7 days:

- One day before chemotherapy
- On the day of chemotherapy
- For five days after chemotherapy

3. The reason why you were chosen

You were invited to join this study because:

- You are an adult cancer patient confirmed by tissue examination.
- Your kidney, liver, and blood tests are within normal limits.
- You are in good daily health condition.
- You are scheduled to receive cisplatin-based chemotherapy.

4. Study procedures

You will be interviewed about your name, age, medical history, medicines you use, allergies, smoking or alcohol habits. You will have a physical examination by a doctor. Blood and urine samples will be taken three times during the study. Blood will be taken using a small needle; about two tubes each time. Urine will be collected in a container provided to you. You will receive study tablets to take with water. Some participants will receive NAC, while others may receive a placebo (a tablet without active medicine). This is to compare the effects fairly.

5. Risk and side effects

N-acetylcysteine is generally safe when taken by mouth. However, some people may experience:

- Nausea or vomiting (due to its strong smell)
- Itching or skin redness
- Rarely, an allergic reaction

If you have any side effects, the study team will arrange for you to see a doctor and provide treatment if needed.

6. Benefits

You will receive free blood and urine tests to check your overall health, liver function, and kidney function.

7. Compensation

You will receive Rp150,000 as compensation for your time and participation.

8. **Confidentiality**

   All your medical and personal information will be kept confidential. Your data will only be used for research purposes.

   Your name will not appear in reports, presentations, or scientific publications. However, authorized parties such as the sponsor, ethics committee, or government regulators may review your data if required.

9. **Your responsibilities**

   As a study participant, you are expected to follow the instructions given by the research team. Please ask questions if anything is unclear.

   During the study, you should not take other medicines or herbal remedies unless approved by the study team.

10. **Your rights**

    Taking part in this study is completely voluntary.

    - You may refuse to join or withdraw at any time, without affecting your medical care at this hospital.
    - If you decide to stop, your relationship with the doctors and your treatment will not be affected.

11. **After the study (Post-trial access)**

    At the end of the study, if you are still receiving cisplatin-based chemotherapy, the research team will provide one additional cycle of your best possible follow-up treatment free of charge.

12. **Additional information**

    If you have questions or experience side effects, please contact:

    Dr. Oryza Gryagus Prabu, Sp.PD

    Phone/WhatsApp: 0821-1113-3822

All of the explanations have been given to me and all of my questions have been answered by Oryza Gryagus Prabu, MD., and the research team. I understand that if I need further explanation I can ask Oryza Gryagus Prabu, MD., and the research team.

Consent Statement	
I have read all the explanations about this study. I have been given an opportunity to ask and all of my questions have been answered clearly. I voluntarily agree to participate in this study. _____ Name of the subject/ legal guardian _____ Signature of the study subject / legal guardian Date_____ day/month/year	I confirmed that the subject has been given the opportunity to ask questions about this study, and all of the questions have been answered clearly. I confirmed that this consent is given voluntarily. _____ Researcher name _____ Signature of the researcher Date_____ day/month/year

Primary investigator contact information:

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