ENGLISH TRANSLATION

Informed consent form

Participant information sheet and blank consent form

OFFICIAL TITLE • ENGLISH TRANSLATION OF THE ETHICS CERTIFICATE TITLE

Evaluation of the Clinical Performance of the Robust Hemodialysis Machine and Wolfgang HD-180 Dialyzer in Patients Receiving Maintenance Hemodialysis at Bethesda Hospital Yogyakarta

NCT number	Unavailable at preparation
Document date	19 December 2025, as printed in the source footer
Version	Version 1, as identified in the source filename
Source	IC Wolfgang ver 1 19 Desember 2025.docx
English translation date	4 November 2026

SOURCE VERSION

This source form describes two study sessions, first with the usual dialyzer and then with the new dialyzer. The latest manuscript describes four scheduled sessions, with the new system first. Verify which approved version participants received before public posting. This translation retains the original procedures and blank signature fields. Telephone numbers are redacted.

Participant information sheet and informed consent form

Evaluation of Dialysis Adequacy and Safety of Switching to a New High-Flux Polyethersulfone Hollow-Fiber Dialyzer (WOLFGANG-HD180) Compared with a Conventional Dialyzer in Patients Receiving Maintenance Hemodialysis at Bethesda Hospital Yogyakarta

This consent form contains important information to help you decide whether to take part in this research.

The study staff will explain the study to you or your guardian. You can ask questions at any time about anything that is unclear. You can take an unsigned copy of this form home to think about it and discuss it with your family, relatives or friends.

Taking part is voluntary. It is your decision. If you join, you may still stop at any time. No one can promise that taking part will help you. Join only after all your questions have been answered.

After reading and discussing this form, you should understand why the research is being done, what will happen during it, the possible benefits and risks to you, whether you may have to pay anything, and what to do if you have a problem or a question about the research.

Please read this consent form carefully.

Study title and investigators

Evaluation of Dialysis Adequacy and Safety of Switching to a New High-Flux Polyethersulfone Hollow-Fiber Dialyzer (WOLFGANG-HD180) Compared with a Conventional Dialyzer in Patients Receiving Maintenance Hemodialysis at Bethesda Hospital Yogyakarta

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Study telephone number: [Telephone number redacted from public copy.]

1. Introduction

You are invited to take part in a research study. Before deciding, it is important to understand why it is being done and what it involves. This form may contain unfamiliar words. Take time to read it carefully. You may take an unsigned copy home and discuss it with your guardian, relatives, study doctor or other primary care physician. Ask the study doctor or a member of the study staff to explain any word or information you do not understand, or to give you more information.

After you have received this information, understood the procedures and had all your questions answered, you will need to decide whether to take part. If you decide to participate, your guardian must first agree to your participation. You and your guardian will then be asked to sign and date this form. You will receive a copy of the signed form.

The Medical and Health Research Ethics Committee has approved the information in this consent document and given the study doctor permission to conduct the research. An institutional review board or ethics committee is an independent committee established to help protect the rights of research participants. Committee approval does not constitute a decision about your own

participation. Consider the information in this form and decide for yourself whether you wish to take part.

2. Purpose of the study

Your study doctor and colleagues are studying a new WOLFGANG dialyzer that uses high-flux polyethersulfone (PES) hollow fibers. The dialyzer is the main filter used in hemodialysis to remove waste products and excess fluid from the body. The new-generation dialyzer is described as more cost-efficient and is claimed to remove uremic toxins, including medium-sized toxins such as beta-2-microglobulin, more effectively than the conventional dialyzer used previously.

The study will examine whether the new dialyzer can maintain or improve the adequacy of dialysis as measured by Kt/V, urea reduction ratio (URR), urea and creatinine. It will also examine whether it improves removal of beta-2-microglobulin, maintains or improves the balance of blood electrolytes (sodium, potassium and calcium), maintains blood albumin as an indicator of the membrane's safety with respect to protein leakage, and avoids acute side effects during dialysis, such as low blood pressure, muscle cramps or allergic reactions.

After the study you will receive all the results of the tests relating to the quality of your dialysis and the uremic toxins in your blood. You will also contribute to efforts to improve the efficiency and effectiveness of dialysis services at Bethesda Hospital Yogyakarta.

2.1 Introduction to the treatment being studied

Life expectancy for people with end-stage kidney disease has increased since regular hemodialysis was introduced. However, people on hemodialysis still have higher rates of illness and death than the general population. The leading cause of death is cardiovascular disease, which is closely associated with malnutrition, chronic systemic inflammation, thickening of the wall of the heart's left ventricle, metabolic disturbances and the buildup of uremic toxins.

Conventional low-flux dialyzers do not optimally clear many of the toxins that accumulate in the blood in kidney failure, particularly medium- to large-sized molecules. These substances include proinflammatory cytokines, beta-2-microglobulin and other mediators. They contribute to inflammation, nutritional problems, impaired immune function and cardiovascular complications.

Beta-2-microglobulin is an extensively studied medium-sized uremic toxin. It is a polypeptide with a molecular weight of about 11.8 kDa. Its accumulation has been associated with a greater risk of dialysis-related amyloidosis, cardiovascular events and death. Its blood concentration is therefore used as a marker of the effectiveness of middle-molecule removal during hemodialysis, particularly when evaluating new dialyzers.

High-flux dialyzers have larger membrane pores and a higher ultrafiltration coefficient (Kuf) to address the limitations of low-flux dialyzers in removing medium-sized toxins. The WOLFGANG dialyzer (PC Series) uses polyethersulfone hollow fibers, radial flow distribution and ultrasonic processing designed to improve the efficiency of diffusion and convection without increasing the risk of albumin loss. WOLFGANG is claimed to improve beta-2-microglobulin clearance while maintaining patient safety and comfort.

Use of high-flux dialyzers in Indonesia is limited, and most people on maintenance hemodialysis still use conventional dialyzers. Local assessment of the effectiveness and safety of high-flux dialyzers is important before they are used more widely. The study will compare dialysis adequacy and beta-2-microglobulin clearance with WOLFGANG and conventional dialyzers. It will also evaluate urea, creatinine, albumin and electrolytes and record possible side effects during hemodialysis.

By comparing measurements before and after the change in the same patients, the investigators hope to provide preliminary information to help select the best dialyzer for patients receiving maintenance hemodialysis at Bethesda Hospital Yogyakarta and other facilities in Indonesia.

2.2 Do I have to take part?

Taking part is entirely voluntary. Declining will not affect your right to medical care at Bethesda Hospital. You may withdraw at any time without giving a reason and without consequences for your treatment or your relationship with the medical team. If you stop, we would appreciate your attending one final evaluation visit. That visit is optional.

Data collected up to the time you withdraw will still be used for the study analysis and will be kept confidential. Your identity will not be included in study reports or publications.

3. Study procedures

Thirty eligible people will be enrolled. Your participation will consist of two hemodialysis sessions during your usual treatment schedule. There will be no change or addition to your dialysis schedule.

The study has a before-and-after design. Each participant will have two study sessions, one week apart. At the first session you will have your usual hemodialysis with the dialyzer you currently use. At the second session you will have hemodialysis with the new high-flux WOLFGANG PES dialyzer.

Blood samples will be taken before and after dialysis at each study session for Kt/V, urea, creatinine, beta-2-microglobulin, albumin, sodium, potassium, calcium and routine blood counts. Your condition will also be monitored during dialysis, including your blood pressure and any side effects such as cramps or allergic reactions.

The two possible schedules for the study sessions are shown below.

Week 1, dialysis day 1	Week 1, dialysis day 2	Week 2, dialysis day 1	Week 2, dialysis day 2
First study session	Usual dialysis	Second study session	Usual dialysis

Or

Week 1, dialysis day 1	Week 1, dialysis day 2	Week 2, dialysis day 1	Week 2, dialysis day 2
Usual dialysis	First study session	Usual dialysis	Second study session

3.1 Main inclusion and exclusion criteria

The study doctor or study staff will discuss the conditions you must meet to participate. Please cooperate and answer questions about your past health honestly. If you do not meet the requirements, you may not participate.

Requirements for participation

1. You are 18 to 75 years old when informed consent is obtained, and your general health is good in the study doctor’s opinion.
2. You agree to take part by signing the informed consent form.
3. You have received regular conventional hemodialysis for at least six months at Bethesda Hospital Yogyakarta.
4. You receive standard heparin for dialysis, do not use a hemodialysis catheter or other device for vascular access, and have a dialysis blood flow rate (Qb) greater than 200 mL/min.
5. You are physically and mentally able to participate and willing to attend the two study dialysis sessions and have the related laboratory tests.
6. A personally signed and dated informed consent document shows that you and your legal representative have been informed about all relevant aspects of the study.

Main reasons you cannot participate

You cannot take part if you meet any of the following exclusion criteria.
1. You have an acute condition associated with end-stage kidney disease or another illness.
2. You have a very low platelet count (below 50,000/µL), a clotting disorder or a bleeding disorder, as determined by the study team.
3. Your white blood cell count is below normal (less than 4,000 cells/µL), as determined by the study team.
4. You have been diagnosed with an immunological disorder or a malignancy (cancer).
5. You have a systemic infection, based on the study doctor’s assessment and examination.
6. The study doctor considers you unsuitable for participation.

Main reasons participation will stop

1. You do not attend or follow the agreed schedule and procedures, for example if you decline a blood draw.
2. You do not wish to continue participating.
3. You experience a serious side effect or a severe allergic reaction while using the new dialyzer.
4. Your condition worsens or becomes acute or unstable, for example because of systemic infection, bleeding or a clotting disorder.

Description of study procedures

Only visits involving study activities such as data collection, examinations or blood sampling are described here. Other visits are routine hospital appointments for your usual dialysis.

First session

At the first session the study doctor will assess your eligibility and provide the first routine dialysis treatment under the study protocol. The doctor will check the inclusion and exclusion criteria, your general health, vascular access and dialysis regimen. The doctor will ask about relevant symptoms, perform a basic physical examination and take a blood sample for routine tests.

If you are eligible, the study will be explained to you in full and you will be asked to sign the informed consent form. Your demographic information, clinical status and medical history will be recorded as baseline information. You will then undergo routine hemodialysis with your usual dialyzer.

Before and after dialysis, blood samples will be collected for urea, creatinine, beta-2-microglobulin, albumin, electrolytes, a complete blood count and calculation of Kt/V and URR. Your blood pressure and any side effects will be monitored during dialysis.

Second session

The second session is one week after the first. You will receive hemodialysis with the new WOLFGANG high-flux polyethersulfone dialyzer. Blood samples will be collected before and after dialysis for urea, creatinine, beta-2-microglobulin, albumin, electrolytes, a complete blood count and calculation of Kt/V and URR. Blood pressure and side effects will be monitored during dialysis.

The team will record the data on a case report form (CRF) and analyze them together with the data from the first session to assess changes associated with the use of the WOLFGANG dialyzer.

4. Benefits to participants

You will receive information about your beta-2-microglobulin, urea, creatinine, albumin, sodium, potassium and calcium levels and your Kt/V and URR values. These measures reflect the adequacy and effectiveness of your hemodialysis. Beta-2-microglobulin is a marker of medium-sized toxins associated with the risk of cardiovascular disease and death. Knowing the level can help you and your doctor better understand how effectively your dialysis is working.

The tests will be performed at no additional cost and the results will be given to you. The study findings may help improve the quality and efficiency of hemodialysis services at Bethesda Hospital Yogyakarta and the choice of more effective, efficient and safe dialyzers for future patients.

5. Your responsibilities

Attend your usual scheduled dialysis sessions during the study. Provide honest information and follow the study team’s instructions. If you wish to withdraw for any reason, tell the study team promptly using the study telephone number in the contact section of this form.

6. Possible side effects

6.1 Risks of using the WOLFGANG high-flux polyethersulfone dialyzer

The WOLFGANG dialyzer has a high-flux polyethersulfone hollow-fiber membrane. High-flux dialyzers such as WOLFGANG are widely used in clinical practice and generally have a favorable safety profile. As with any hemodialysis treatment, the following side effects may occur.

• A drop in blood pressure during dialysis, especially if you already have low blood pressure or excess fluid.
• Muscle cramps, dizziness, nausea or discomfort during dialysis.
• Allergic reactions to the dialyzer membrane. These are rare and may include itching or a rash. Very rarely, a severe reaction such as shortness of breath or anaphylaxis may occur.
• Protein loss, including albumin. This is generally minimal with high-flux dialyzers but will be monitored by laboratory testing.

The study medical team will monitor you during and after dialysis and provide immediate treatment if an unwanted reaction occurs.

6.2 Risks of study procedures

Blood sampling can cause mild discomfort, bruising or a hematoma. The amount of blood taken, about 10 mL per sample, will not cause systemic symptoms. After a blood draw, press on the site on your arm for 5 to 10 minutes. Do not rub it, to avoid bruising or a hematoma. Sterile procedures will be followed at the blood draw and vaccine injection sites to prevent infection.

7. What benefits might I gain by taking part?

You will receive information on how effectively uremic toxins are removed, including your beta-2-microglobulin level and other measures of dialysis adequacy. You will have additional laboratory tests at no cost, including urea, creatinine, albumin, electrolytes, calcium and a complete blood count. You will contribute to improving dialysis care for other patients at Bethesda Hospital and in Indonesia.

8. Costs of taking part

The investigators will cover the full cost of all study procedures, including blood sampling, additional laboratory tests and data recording. Neither you nor your insurer will be charged.

9. Reimbursement or compensation for taking part

In appreciation, you will receive Rp50,000 for transportation per study session (two sessions in total) and a light snack after dialysis at each study session.

10. Alternatives to participation

You may continue your usual maintenance hemodialysis without joining the study. Your decision will not affect the medical care you receive.

11. Compensation for injury

Blood sampling is commonly performed and generally has no significant side effects. In some people, bleeding under the skin after a blood draw resolves by itself within a few days. This may happen if a small blood vessel breaks during sampling. If you develop a bruise or hematoma at the blood-draw site, you will be given Thrombophob. If other side effects occur, the medical team will manage them according to hospital standards.

12. Privacy and confidentiality of study records and medical records

If you agree to participate, your identity and medical records will be kept confidential. They will not be disclosed outside the hospital, clinic or family doctor’s practice unless the law requires it. The study staff will assign you a participant number that does not reveal your name, identity number, address or other identifying details. Your identity will remain confidential if the findings are published.

By signing, you also agree that monitors, auditors, ethics committee members and regulatory authorities may review your original medical records to ensure that the study procedures and data comply with laws and regulations. They undertake to maintain confidentiality and avoid disclosing your identity. All of these individuals will protect your privacy while respecting the authorities’ right to review the records.

13. What will happen to the results?

Once the study has ended, the information will be analyzed and the results recorded in a study report. This may take several months. Your study doctor will keep you informed of the findings. A paper describing the results may be published in an appropriate medical journal. After the study ends you may also contact the study doctor to ask for the results.

14. Voluntary participation and withdrawal

Your participation is entirely voluntary. You may choose not to take part or may leave at any time. Your decision will not result in a penalty or the loss of benefits to which you are entitled. Tell the study doctor if you are thinking about stopping or have decided to stop. The doctor will explain how to stop safely. If you withdraw, please inform the team by text message or telephone using the study contact number in this form.

15. Early termination of the study

The study doctor may stop your participation without your consent if this is in your interest or if you cannot follow the protocol, for example if you do not attend clinical visits.

16. Your rights

If you have questions, concerns or complaints about how the study will be conducted or your participation, or if you believe at any time that you have experienced a research-related injury, you may contact the study doctor listed in this consent form.

If you have questions about your rights as a research participant or concerns or complaints about the study, you may write to the Medical and Health Research Ethics Committee, Jl. Farmako, Sekip Utara, Yogyakarta 55128, or telephone [telephone numbers redacted from public copy] during office hours, Monday to Friday, 08:00 to 16:00.

This consent form has been prepared in duplicate. The doctor has given you a copy and explained the nature and purpose of the study. After the study ends, we will tell you about any unexpected safety issue that could directly affect you.

Participant’s statement of consent

I confirm that I have read this consent form (or that it has been read to me) and that its contents have been explained to me. I have had an opportunity to ask questions, and all my questions have been answered to my satisfaction. I agree to participate and to follow the study requirements as well as I can.

I understand that my participation is voluntary and that I am free to withdraw at any time without giving a reason and without affecting my health care or legal rights.

I agree to take part in the study described above.

I agree that all anonymous data collected from me during the study may be used, individually or combined with data from other participants, in the study analysis, in printed publications or for other purposes.

By signing this form, I have not given up my legal rights.

Participant’s full name

Participant’s signature

Date

Time

Statement of the person conducting the informed consent discussion

I, the undersigned, declare that, to the best of my knowledge, the participant named above has received a full and careful explanation of the study, including its nature and the risks and benefits of participation. All questions have been answered to the participant’s satisfaction. I confirm that the participant freely and voluntarily consented before any study procedures took place. Medical conditions, language or educational barriers did not prevent understanding.

I reviewed the form with the participant and answered their questions. The participant appeared to understand the information and could correctly answer the following questions.

1. What is the purpose of this study?
2. If you decide to take part, what will you be asked to do?
3. What benefits might you receive from taking part?
4. What risks might arise from taking part?
5. Will taking part cost you anything? If it will, what must you pay for?
6. Do you have to take part?
7. If you decide to take part, can you leave the study at any time?

Signature of the person conducting the informed consent discussion

Date

Time

Name of the person who explained the consent form, if different from the investigator

I, the undersigned, declare that, to the best of my knowledge, the participant named above has received a full and careful explanation of the study, including the nature, risks and benefits of participation.

Investigator’s signature, if different from the person above

Date

Time

Witness section to be used only when applicable

If this authorization form is read aloud because the participant cannot read it, an impartial witness who is independent of the investigator and the study must be present during authorization and sign the statement below.

I confirm that the information in this authorization form and any other written information was accurately explained to the participant, who appeared to understand it. The participant freely agreed to take part in this study.

Name of the impartial witness

Signature of the impartial witness

Date

Note from the source form: This signature block cannot be used for translation into another language. A translated authorization form is required to enroll participants who do not speak English.

The original copy is to be kept by the investigator, one copy given to the participant, and one copy filed in the participant’s medical record.