**Participant Consent Form**

**Title of Study:** *LoW Dose-Intensity vs. Standard Dose-Intensity COntinuous Renal ReplaceMent Therapy in Critically Ill Patients (WISDOM): A Pilot Randomized Trial*

**Principal Investigator:** Dr. Sean Bagshaw Telephone: 780-492-8597

*In the case of third-party consent, ‘you’ always refers to the research participant. The pronouns ‘you’ and ‘your’ should be read as referring to the participant rather than the parent/guardian/next-of-kin who is signing the consent for the participant.*

**WHY AM I BEING ASKED TO TAKE PART IN THIS RESEARCH STUDY?**

You are being asked to be in this study because you have been started on acute renal replacement therapy (dialysis) by your intensive care unit (ICU) medical team to support your kidneys during your critical illness. This study is being performed because we are uncertain of the acceptable dose of dialysis therapy that should be prescribed in patients such as you who are receiving acute dialysis therapy in the ICU.

Before you decide, a member of the research team will go over this form with you. You are encouraged to ask questions if you feel anything needs to be made clearer. You will be given a copy of this form for your records.

**WHAT IS THE REASON FOR DOING THE STUDY?**

Sick patients who are admitted to the ICU need advanced life support. A common type of life support is acute renal replacement therapy (also called dialysis) to support injured kidneys and other organs. We are not certain of the minimum acceptable dose to be prescribed for patients who are receiving acute dialysis therapy in the ICU. In this circumstance, the term “dose” refers to the “intensity” of how your blood will be cleaned during the process of receiving dialysis therapy.

Prior studies have found that sick patients in the ICU who receive more-intensive (higher) dose dialysis have similar survival and need for outpatient (long-term) dialysis therapy to patients who receive less-intensive (standard) dose dialysis. In these studies, both the higher and the standard dialysis therapy achieved similar control of fluid, acid and electrolytes in the body and prevented complications due to kidney failure. However, the higher dose dialysis may have resulted in a need for patients to be on dialysis longer and have a lower chance of recovering their kidney function. In addition, the higher dose dialysis did require more work for bedside nurses and was more expensive.

The purpose of the WISDOM trial is to compare two different doses of dialysis that are currently prescribed in usual care. The WISDOM trial will compare a lower

dose with a more standard dose of acute dialysis therapy in sick patients in the ICU who the ICU medical team have determined require dialysis.

The WISDOM trial is a preliminary study that will aim to include 100 patients admitted to selected ICUs in Edmonton, and possibly across Alberta and Canada. We plan to enroll 40-50 patients admitted to the General Systems Intensive Care Unit at the University of Alberta Hospital.

**WHAT WILL HAPPEN IN THE STUDY?**

As part of the process to determine if you were eligible for this study, we have assessed whether your ICU medical team have started you (or will shortly start you) on dialysis therapy.

If you are eligible to participate and have been started on acute dialysis therapy (or about to be), you will be assigned to one of two treatment groups, by random selection (like flipping a coin):

* One group will receive a ***lower dose of dialysis*** therapy.
* The other group will receive a ***standard dose of dialysis*** therapy.

If you are allocated to ***lower dose of dialysis*** therapy, you will have your dialysis dose adjusted to target the lower dose range of current practice following a minimum of 12 hours at the standard dose of dialysis and once enrollment in the study is completed.

If you are allocated to the ***standard dose of dialysis*** therapy, you will have your dialysis dose adjusted (if necessary) to the usual dose range of current practice and maintained at the standard dose of dialysis for the duration of your enrollment in the study.

Regardless of which group you have been assigned to, you will undergo the same procedures and receive the same general care. The only difference between the two groups will be the dose of dialysis therapy you receive while you are in the ICU.

While you are enrolled in the study, your vital signs and blood work will be watched closely while you are supported in the ICU.

If you require dialysis beyond your time in the ICU, you will be transitioned to a different form of dialysis therapy that can be delivered intermittently, such as every other day or three times per week. This form of dialysis therapy will be guided by kidney doctors and is not part of this study.

**WHAT ARE THE RISKS AND DISCOMFORTS?**

Dialysis therapy is commonly used in the ICU to support patients like you whose kidneys are not working normally. The decision to start and discontinue dialysis therapy will be made by your ICU medical team and aligned with current procedures for best practice. Both doses of acute dialysis in this study are within the range of current practice and are likely to be adequate. However, a risk to you, if you are allocated to the lower dose dialysis arm, would be that your dialysis therapy would not be sufficient to clean your blood of metabolic waste and toxins. This would be determined by close monitoring of routine blood work that you receive as standard of care while in the ICU. If your ICU medical team believes that this is occurring and that an increase in your dose of dialysis is needed and in your best interests, this can be easily and immediately adjusted and implemented.

**WHAT ARE THE BENEFITS TO ME?**

You may or may not have any direct benefit by taking part in this study. This study is designed to assess which dose of dialysis, lower or standard, is safer and more effective. Preliminary evidence has suggested that lower doses of acute dialysis may be associated with more rapid recovery of kidney function and ability to stop dialysis therapy; however, this remains to be proven. At minimum, if both doses of dialysis are found to have similar safety and effectiveness, this would guide practice for future patients by prescribing the least intensive and less costly option.

**WHAT WILL I BE ASKED TO DO WHILE I AM IN THE STUDY?**

You will not be asked to do anything specific to participate in the study while you are in the ICU. During this time, the research team will record health information about you. The research team may ask you questions about your health; however, this is usually done by reviewing your health record. After you are discharged from the ICU, the research team would like permission to have a member of the research team to contact you by telephone to ask you some questions about your health approximately 30 days and 90 days after starting the study. This would take no longer than about 10 minutes. No additional tests, beyond that mentioned above, will be done. This study will not require any added time from you.

**WHAT HAPPENS IF I AM INJURED BECAUSE OF THIS RESEARCH?**

If you become ill or injured because of being in this study, you will receive necessary medical treatment, at no additional cost to you. By signing this consent form you are not releasing the investigator(s), institution(s) and/or sponsor(s) from their legal and professional responsibilities.

## DO I HAVE TO TAKE PART IN THIS STUDY?

Your decision to take part in this study is your choice. You may choose to participate, or you may not. This decision will in no way affect the care you receive in the ICU.

**CAN MY PARTICIPATION IN THE STUDY END EARLY?**

If you decide to be in the study, you can change your mind and stop being in the study at any time, and it will in no way affect the care or treatment that you are entitled to. If your ICU medical team or the research team feel that it is in your best interest to withdraw you from the study, they will remove you without your consent. If the study sponsor decides to end the study early, for any reason, you may also be removed from the study without your consent. We will tell you about any new information that may affect your health, welfare, or willingness to stay in this study.

**ARE THERE OTHER CHOICES TO BEING IN THIS RESEARCH STUDY?**

You may choose not to participate in this study. If you choose not to participate, the care you receive while in the ICU, including your treatment with acute dialysis therapy, will not be limited in any way and will continue as usual care prescribed by your ICU medical team.

**WHAT WILL IT COST ME TO PARTICIPATE?**

There will be no additional costs to you for participating in this study.

**WILL I BE PAID TO BE IN THE RESEARCH?**

You will receive no payment for taking part in this study.

**PRIVACY AND CONFIDENTIALITY**

During the study we will be collecting health information about you. We will do everything we can to make sure that this data is kept private. No data relating to this study that includes your name or identifying information will be released outside of the study doctor’s office or published by the researchers. Sometimes, by law, we may have to release your information with your name so we cannot guarantee absolute privacy. However, we will make every legal effort to make sure that your health information is kept private.

**WHAT DATA WILL WE BE COLLECTING?**

Information about your demographics, past medical history, current hospital admission, and treatment will be recorded for this study by the research team. This information will be collected either directly from you or from your health records, including your electronic medical record. The researchers may need to access your health records up to 1 year after the study is complete to confirm and verify any specific health information directly related to your participation in the study. This may include obtaining your health information stored in administrative databases maintained by Alberta Health and Alberta Health Services.

**HOW WILL THE STUDY DATA BE STORED?**

The study data we collect, which will include your name, will be securely stored by the research team during and after the study. We will also put a copy of this consent form in your medical record, so that doctors you see in the future will know you were in the study. In Canada, the law says we must keep the study data stored for at least 15 years after the end of the study.

The research team will not release your name to anyone unless the law says that they have to.

**HOW WILL THE STUDY DATA BE USED?**

Your study data will be coded (with a number) so that it no longer contains your name, address, or anything else that could identify you. Only the research team will be able to link your coded study data to you. This coded study data will be kept secure and will be used now and in the future to:

* Learn more about the tolerance, safety and effectiveness of the study intervention,
* Learn more about how to best treat your illness.

When the study is done, the research team may place your coded study data into a secure database. The coded data may then be used to answer other related research questions in the future. Only the research team who have the training and experience to do the research (also known as “qualified researchers”) will be allowed to use these data.

**WHO WILL BE ABLE TO LOOK AT MY HEALTH DATA?**

During research studies it is important that the data we get is accurate. For this reason, your health data, including your name, may be looked at by people from: the study sponsor, the University of Alberta auditors, members of the Research Ethics Board and Health Canada.

By signing this consent form you are saying it is okay for the research team to collect, use and disclose information about you from your personal health records, including electronic health records and administrative databases, as described above.

If you would like to see the study data collected about you, please ask the research team. You will be able to look at the study data about you and you can ask for any mistakes to be corrected. The research team may not be able to show you your study data right away and you may have to wait until the study is completed or another time in the future before you can see your study data.

If you leave the study, we will not collect new health information about you, but we will need to keep the data that we have already collected.

**CONTACT INFORMATION:**

If you have further questions concerning matters related to this research, please contact:

Dr. Sean M Bagshaw, **780-492-8597**

Research Coordinator **780-492-9951**

If you have questions or concerns about your rights as a study participant, you may contact the **Research Ethics Office** of The University of Alberta at **780-492-2615**. This office is independent of the study investigators.

**HOW DO I INDICATE MY AGREEMENT TO BE IN THE STUDY?**

By signing below, you understand:

* That you have read the above information and have had anything that you do not understand explained to you to your satisfaction
* That you will be taking part in a research study
* That you may freely leave the research study at any time
* That you do not waive your legal rights by being in the study
* That the legal and professional obligations of the investigators and involved institutions are not changed by your taking part in this study.

**SIGNATURE OF STUDY PARTICIPANT**

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Signature of Participant

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Name of Participant Date

**SIGNATURE OF PERSON OBTAINING CONSENT**

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Signature of Person Obtaining Consent

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Name of Person Obtaining Consent Date

**SIGNATURE OF THE WITNESS**

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Signature of Witness

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Name of Witness Date

*A signed copy of this consent form has been given to you to keep for your records and reference.*