The Ohio State University Combined Consent to Participate in Research and HIPAA Research Authorization

- **Study Title:** Prospective Validation of Readmission Risk Score in Predicting Early Readmissions in Patient with Decompensated Cirrhosis In a Tertiary Medical Center
- **Principal Investigators:** Khalid Mumtaz, MBBS, MSc | Division of Gastroenterology, Hepatology and Nutrition & Antoinette Pusateri, MD | Department of Internal Medicine
- **Sponsor:** The Ohio State University

- **This is a consent form for research participation.** It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to participate.
- **Your participation is voluntary.** You may refuse to participate in this study. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will not affect your future relationship with The Ohio State University. If you are a student or employee at Ohio State, your decision will not affect your grades or employment status.
- **You may or may not benefit as a result of participating in this study.** Also, as explained below, your participation may result in unintended or harmful effects for you that may be minor or may be serious depending on the nature of the research.
- **You will be provided with any new information that develops during the study that may affect your decision whether or not to continue to participate.** If you decide to participate, you will be asked to sign this form and will receive a copy of the form. You are being asked to consider participating in this study for the reasons explained below.

Key Information About This Study
The following is a short summary to help you decide whether or not to be a part of this study. More detailed information is listed later in this form.

Cirrhosis is a chronic progressive disease of the liver. Patients with decompensated cirrhosis (DC) have a high rate of readmission to the hospital due to their complex disease. Our research team has previously made a readmission risk score using data from patients across the United States with DC. In this study we want to look at our risk score in our institution's inpatient hepatology and hepatology consult services for one year (July 1st, 2019 until May, 31st, 2020) and improve its ability of prediction by collecting more information about patients' medical history, physical exam, lab values, and medicines they are on for cirrhosis. Being able to predict which patients are at higher risk for readmission could allow us to

prevent such readmissions, which would likely reduce the cost of care, improve quality of life and decrease risk of death in patients with DC.

If you agree to participate in this study, we will collect data from your electronic medical record. At the time of study consent, we will assess your physical strength and will ask you to complete a quality of life survey. You will be randomly assigned (like the flip of a coin) into a standard of care or intervention arm. Either way you will be called by one of our nurse case managers weekly for 4 weeks after your first admission. As part of your standard of care by the OSUWMC liver team, you will be on all the liver medications you need, get follow up with your liver doctor, and, if needed, get an outpatient large volume paracentesis (removal of fluid from your belly). Additionally, if you are in the intervention arm, the nurse case manager will ensure that you are on the liver medications you need to be on, will arrange your hospital follow up visits with your outpatient liver doctor and interventions such as outpatient large volume paracentesis if applicable.

There are minimal risks in this study. You may be asked questions that are sensitive in nature, such as those related to your quality of life. You do not have to answer questions that you are not comfortable answering. Details of your health history and how you got cirrhosis may be sensitive to you, but this is information that does not have to be discussed with the nurse case manager who calls you and will be securely stored in a confidential research study database. You do not have to participate and the care you receive will not be affected whatsoever.

1. Why is this study being done?

Cirrhosis is a chronic, progressive disease of the liver that has complex medical consequences that often need hospitalization. Studies show that after the first hospitalization, between 20% and 40% of patients are readmitted within 1 month, with more than half being readmitted within 3 months. Readmission to the hospital not only impacts quality of life for patients and families but has been shown to be a predictor of death. Furthermore, hospital readmissions in general are a large financial burden on the United States healthcare system, especially readmissions for cirrhosis related issues. In the United States in 2014, hospitalizations for cirrhosis added up to $4 billion in total costs with an average charge per initial stay of $29,692 and an average charge per readmission of $30,607.

Due to the physical, emotional and financial burden of readmission for cirrhosis, we created a re-admission risk score that helps us to predict 30-day readmission. In this study, we seek to make our risk score by following patients in real time to see if they are readmitted. Through analyzing a patient's readmission rate, we can confirm and improve the accuracy of our risk score. In the future we can organize programs aimed at reducing and preventing hospital readmissions, especially for those patients with cirrhosis predicted to be high risk for readmission.

You are being asked to participate in this research study because you have cirrhosis of the liver and have been admitted to The Ohio State University Wexner Medical Center Hepatology Service or received care from the Hepatology Consult service during time of the study.

2. How many people will take part in this study?

We estimate that 848 patients will participate in this study, all of whom had initial admissions for decompensated cirrhosis at OSUWMC on the hepatology service or on hepatology consults. We will also be recruiting up to 100 patients from Charleston Area Medical Center from Charleston, West Virginia, though they will not have access to your data.

3. What will happen if I take part in this study?

If you want to take part in the study, we will ask you to sign this consent form before we do any study measures.

If you agree to participate in the study, our study team will collect several pieces of information. We will collect this information with your permission from your electronic medical record, including demographic, clinical and follow up data.

4. How long will I be in the study?

The study will run from July 1st, 2019 until May, 31st, 2020. You will be called by one of our nurse case managers weekly for 4 weeks after discharge from your initial admission. Research data will be kept in our secure records for 3 years after study publication and then destroyed.

5. Can I stop being in the study?

You may leave the study at any time. If you decide to stop participating in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with The Ohio State University.

Data collected about the participant prior to withdrawal may be reviewed by the research even if the participant does not provide consent for continued follow-up.

6. What risks, side effects or discomforts can I expect from being in the study?

There are minimal risks in this study. You may be asked questions that are sensitive in nature, such as those related to your quality of life. You do not have to answer questions that you are not comfortable answering.

Also, elements of your health history and how you developed your cirrhosis may be sensitive to you. This is information that does not have to be discussed with the individual consenting you for the study or with the nurse case manager who calls you, but will be collected by the study team using your electronic medical record. While there is a potential risk of exposure of personal health information collected from the electronic medical record, all efforts will be made to prevent this risk by using encrypted research study database stored on secure medical center computers and store the paper consent forms and data collection forms in locked

cabinets in our secured research office in the Division of Gastroenterology, Hepatology, and Nutrition and Clinical Research Center. All study staff are held to the highest standard of confidentiality as dictated by the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

7. What benefits can I expect from being in the study?

We cannot promise that you personally will receive any health benefits from being in this study. With being in the intervention arm, you will get assistance arranging hospital follow up visits with your outpatient hepatologist and interventions such as large volume paracentesis (removal of fluid from your belly) if applicable. This may or may not benefit you.

Overall, the results of this study may lead to our ability to predict those patients with cirrhosis at high risk for readmission. This information could help us develop programs aimed at reducing and preventing readmissions in such patients.

8. What other choices do I have if I do not take part in the study?

You may choose not to participate without penalty or loss of benefits to which you are otherwise entitled.

9. What are the costs of taking part in this study?

While there are no additional costs of taking part in the study, all care you receive as part of your clinical care will not be paid for by the study.

Do consider that one of our nurse case managers will be briefly calling you once a week for 4 weeks following initial admission. We will not be supplying funding for phone calls.

10. Will I be paid for taking part in this study?

You will not be paid to participate in the study.

11. What happens if I am injured because I took part in this study?

We do not anticipate you will be injured from participating in this study. If you should suffer an injury from participating in this study, you should notify the researcher or study doctor immediately, who will determine if you should obtain medical treatment at The Ohio State University Wexner Medical Center. The cost for this treatment will be billed to you or your medical or hospital insurance. The Ohio State University has no funds set aside for the payment of health care expenses for this study.

12. What are my rights if I take part in this study?

If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights you may have as a participant in this study.

You will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.

You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled.

An Institutional Review Board responsible for human subjects research at The Ohio State University reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of research participants.

13. Will my de-identified information be used or shared for future research?

Data collected from this study may be used to help us answer other research questions. Research data will be kept in our secure records for 3 years after study publication and then destroyed.

14. Will my study-related information be kept confidential?

Efforts will be made to keep your study-related information confidential. However, there may be circumstances where this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law.

Also, your records may be reviewed by the following groups:
- Office for Human Research Protections
- The Ohio State University Institutional Review Board or Office of Responsible Research Practices;
- The sponsor supporting the study, their agents or study monitors

Clinically relevant research results will be reported in a combined report and sent in a letter at the time of study publication so that the results from the information collected in the study can be made known to those who participated.

15. HIPAA AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

I. What information may be used and given to others?

- Past and present medical records;
- Research records;
- Records about phone calls made as part of this research;

- Information that includes personal identifiers, such as your name, or a number associated with you as an individual;
- Information gathered for this research about:
    - Demographic information
    - Initial admission and readmission hospitalization data
    - Medical history including surgical, social, family history
    - HIV / AIDS status
    - Hepatitis infection
    - Sexually transmitted diseases
    - Other reportable infectious diseases
    - The diagnosis and treatment of a mental health condition
    - Physical exams
    - Laboratory, x-ray, and other test results
    - Procedure or surgery notes
    - Physician notes
    - Medication list
    - Physical Therapy/Strength evaluation notes – including frailty score if performed
    - Questionnaires including SIPAT - Stanford Integrated Psychosocial Assessment for Transplant (SIPAT) score, a tool commonly used in our Division of Hepatology to assess psychosocial health of patients with cirrhosis regardless of transplant status.
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II. Who may use and give out information about you?

Study staff and researchers will be the only ones with access to previously mentioned information collected about you.

III. Who might get this information?

- The sponsor of this research. "Sponsor" means any persons or companies that are:
    - working for or with the sponsor; or
    - owned by the sponsor.
- Authorized Ohio State University staff not involved in the study may be aware that you are participating in a research study
- If this study is related to your medical care, your study-related information may be placed in your permanent hospital, clinic, or physician's office record

IV. Your information <u>may</u> be given to:

- Governmental agencies to whom certain diseases (reportable diseases) must be reported; and

- The Ohio State University units involved in managing and approving the research study including the Office of Research and the Office of Responsible Research Practices.

V. Why will this information be used and/or given to others?

- To do the research;
- To study the results; and
- To make sure that the research was done right.

VI. When will my permission end?

This permission will be good until 3 years after publication of this research.

VII. May I withdraw or revoke (cancel) my permission?

Yes. Your consent will be good for the time period indicated above unless you change your mind and cancel it in writing. You may take away your permission to use and disclose your health information at any time. You do this by sending written notice to the researchers. If you take back your permission, you will not be able to stay in this study. When you take back your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

VIII. What if I decide not to give permission to use and give out my health information?

Then you will not be able to be in this research study and receive research-related treatment. However, if you are being treated as a patient here, you will still be able to receive care.

IX. Is my health information protected after it has been given to others?

There is a risk that your information will be given to others without your permission. Any information that is shared may no longer be protected by federal privacy rules.

X. May I review or copy my information?

Signing this authorization also means that you may not be able to see or copy your study-related information until the study is completed.

16. Who can answer my questions about the study?

For questions, concerns, or complaints about the study, if you feel you have been harmed as a result of study participation, or if you wish to withdrawal from the study, you may contact: Dr.

Khalid Mumtaz MBBS, MSc, study primary investigator | 614-293-6255 | khalid.mumtaz@osumc.edu |
Division of Gastroenterology, Hepatology and Nutrition
The Ohio State University Wexner Medical Center
395 West 12th Ave., 3rd Floor
Columbus, OH 43210

For questions related to your privacy rights under HIPAA or related to this research authorization, please contact Jen Elliot, HIPAA Privacy Officer | 614-293-4477 | Elliot.481@osu.edu |
HIPAA Privacy Officer
Suite E2140
600 Ackerman Road
Columbus, OH 43201

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact the Office of Responsible Research Practices at 1-800-678-6251.

If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact Sandra Meadows, Research Related Concerns | 614-688-8641 | meadows.8@osu.edu.

17. Permission to speak to family members

By initialing next to one of the options below, I am indicating whether or not the case manager calling to speak to me does or does not have permission to a family member:

_____ Yes, you have my permission to talk with my relative if I cannot answer/am unavailable at my own number listed here:_____

_____ Additionally, I wish to provide my relative's numbers as well as my own:_____

_____ No, you may only talk to me for the research calls

Signing the consent form

I have read (or someone has read to me) this form, and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this combined consent and HIPAA research authorization form**.**

Printed name of subject	**Signature of subject**
	AM/PM
	Date and time
Printed name of person authorized to consent for subject (when applicable)	**Signature of person authorized to consent for subject (when applicable)**
	AM/PM
Relationship to the subject	**Date and time**

Investigator/Research Staff

I have explained the research to the participant or his/her representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.

Printed name of person obtaining consent	**Signature of person obtaining consent**
	Date and time **AM/PM**

Witness(es) - *May be left blank if not required by the IRB*

Printed name of witness	**Signature of witness**
	Date and time **AM/PM**
Printed name of witness	**Signature of witness**
	Date and time **AM/PM**