Supplemental Table 1. Study ICU features

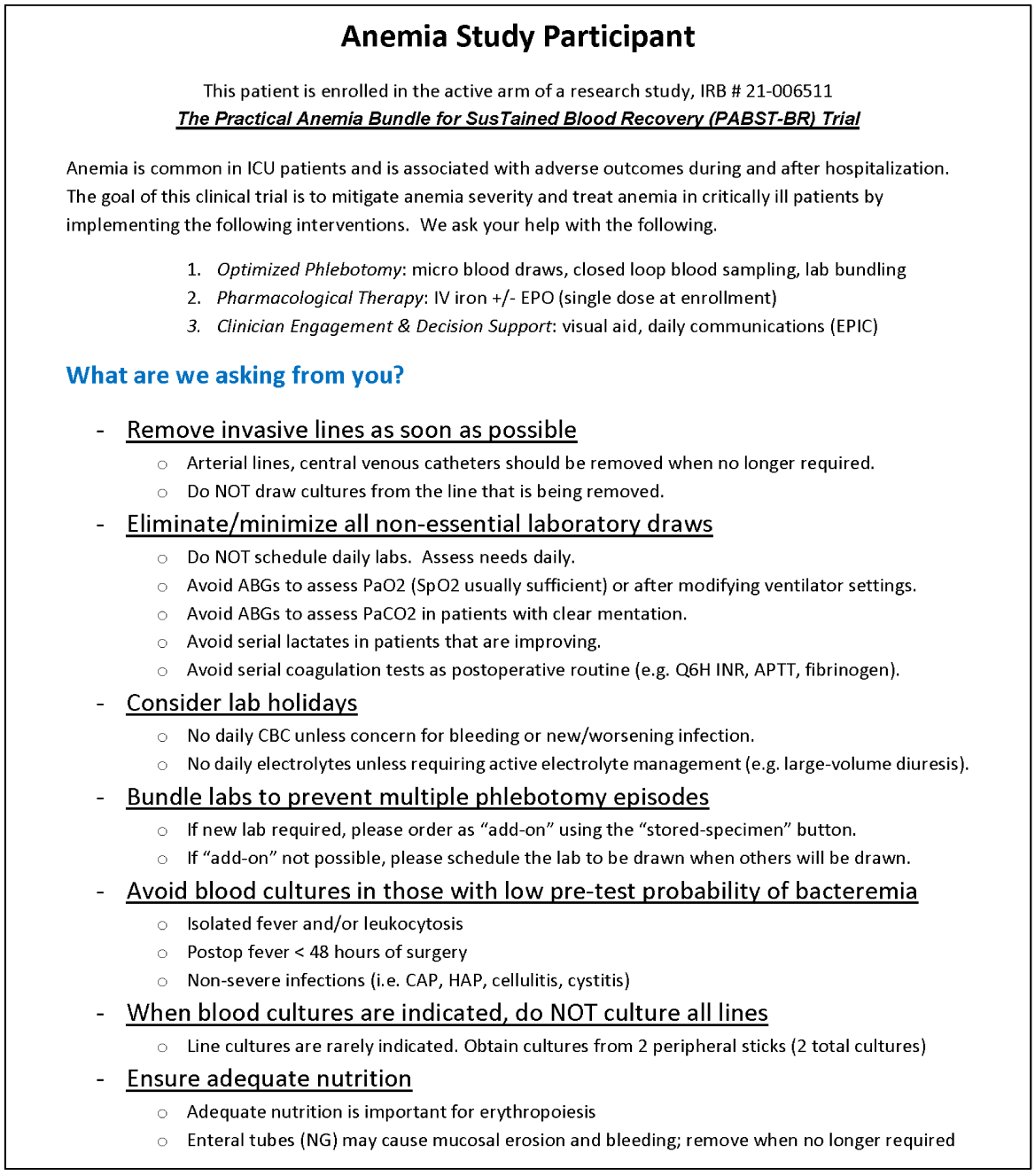
	# of Adult Beds	Typical patients
Cardiac ICU	10	Acute coronary syndromes, heart failure
Cardiovascular Surgical and Transplant ICUs	32	Post-cardiac surgery, post-heart transplant, post-lung transplant, ECMO
Medical ICU	32	Acute respiratory failure, gastrointestinal bleeding, undifferentiated shock
Multispecialty ICU	18	Post-thoracic surgery, post-vascular surgery, medical ICU overflow
Surgical Trauma ICU	12	Trauma, post-general surgery
Neuroscience ICU	18	Status epilepticus, stroke, post-neurological surgery

Supplemental Table 2. Schedule of study activities

Procedures	Enrollment/ Baseline Study day 1	Daily visits throughout hospitalization	Hospital Discharge	1-month post-hospitalization +/- 7 days	3-months post-hospitalization +/- 14 days	12-months post-hospitalization EMR review
Informed consent	X					
Demographics	X					
Medical history	X					
Randomization	X					
Administer study intervention	X					
Vital signs- (BP, HR, RR, O2 sat)	X					
Height	X					
Weight	X		X			
Pregnancy test if needed	X					
Anemia labs[a]	X	X	X	X	X	
Platelet count[d]	X		X			
White blood cell count[d]	X		X			
Creatinine[d]	X		X			
Functional outcome assessment [b]	X		X	X	X	
Medication review [c]	X	X				
Fluid balance	X		X			
RBC transfusions documented	X	X	X	X	X	
Daily phlebotomies for labs		X	X			
Fatigue assessment			X	X	X	
AE review and evaluation	X	X	X	X	X	
Research Samples[e]	X			X	X	
Hospital readmissions documentation				X	X	X
All cause mortality status						X
Complete Case Report Forms	X	X	X	X	X	X

a. **Hemoglobin, ferritin, and transferrin saturation will be obtained for all patients at enrollment, hospital discharge, 1-month, and 3-months post-hospitalization.**
Other anemia labs to be reported at these and other timepoints include, if available Hemoglobin, MCV, RDW, ferritin, iron, transferrin saturation, reticulocyte hemoglobin, absolute reticulocyte count; record all values available recognizing that not all non-hemoglobin values will be available at each interval.
b. Functional outcomes according to the Core Outcome Measurement Set will be obtained in the following fashion: **Enrollment** – ADL survey (by patient or proxy); at **Hospital discharge** – EQ-5D, FACIT-Fatigue; **at 1-month and 3-months** – EQ-5D, FACIT-Fatigue, 6MWD, ADL Survey, MoCA-BLIND, HADS, IES-R.
c. Concomitant meds review to include antiplatelet agents (i.e. aspirin, clopidogrel), anticoagulants (i.e. heparin, warfarin, direct oral anticoagulants, low molecular weight heparins), iron, and erythropoiesis stimulating agent use (i.e. darbepoetin, EPO). Daily visits only need to report if they received iron or EPO/darbepoetin.
d. Baseline results should be from within 24 hrs prior to enrollment. Hospital discharge results used should be the closest to discharge up to 72 hours prior.
e. Research samples (5 ml phlebotomy) will be obtained at enrollment, 1-month, and 3-months and stored for potential biomarker assessment for future mechanistic studies on anemia development and recovery in critical illness survivors.

Supplemental Figure 1. Visual aid for the intervention arm.



Anemia Study Participant

This patient is enrolled in the active arm of a research study, IRB # 21-006511

The Practical Anemia Bundle for SusTained Blood Recovery (PABST-BR) Trial

Anemia is common in ICU patients and is associated with adverse outcomes during and after hospitalization. The goal of this clinical trial is to mitigate anemia severity and treat anemia in critically ill patients by implementing the following interventions. We ask your help with the following.

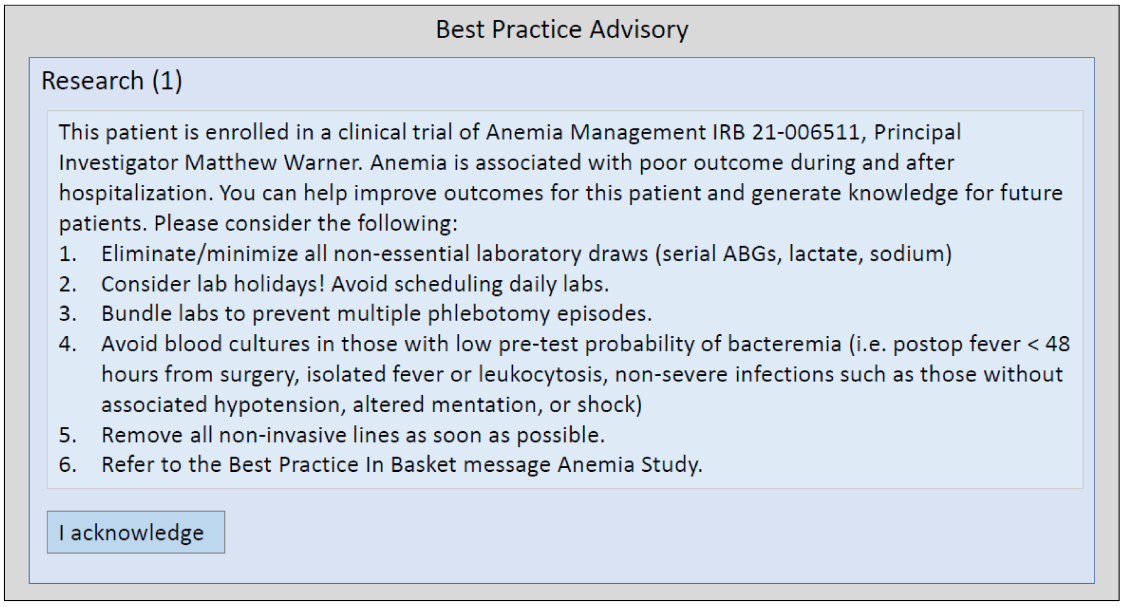
1. *Optimized Phlebotomy*: micro blood draws, closed loop blood sampling, lab bundling
2. *Pharmacological Therapy*: IV iron +/- EPO (single dose at enrollment)
3. *Clinician Engagement & Decision Support*: visual aid, daily communications (EPIC)

What are we asking from you?

- Remove invasive lines as soon as possible
  - Arterial lines, central venous catheters should be removed when no longer required.
  - Do NOT draw cultures from the line that is being removed.
- Eliminate/minimize all non-essential laboratory draws
  - Do NOT schedule daily labs. Assess needs daily.
  - Avoid ABGs to assess PaO2 (SpO2 usually sufficient) or after modifying ventilator settings.
  - Avoid ABGs to assess PaCO2 in patients with clear mentation.
  - Avoid serial lactates in patients that are improving.
  - Avoid serial coagulation tests as postoperative routine (e.g. Q6H INR, APTT, fibrinogen).
- Consider lab holidays
  - No daily CBC unless concern for bleeding or new/worsening infection.
  - No daily electrolytes unless requiring active electrolyte management (e.g. large-volume diuresis).
- Bundle labs to prevent multiple phlebotomy episodes
  - If new lab required, please order as "add-on" using the "stored-specimen" button.
  - If "add-on" not possible, please schedule the lab to be drawn when others will be drawn.
- Avoid blood cultures in those with low pre-test probability of bacteremia
  - Isolated fever and/or leukocytosis
  - Postop fever < 48 hours of surgery
  - Non-severe infections (i.e. CAP, HAP, cellulitis, cystitis)
- When blood cultures are indicated, do NOT culture all lines
  - Line cultures are rarely indicated. Obtain cultures from 2 peripheral sticks (2 total cultures)
- Ensure adequate nutrition
  - Adequate nutrition is important for erythropoiesis
  - Enteral tubes (NG) may cause mucosal erosion and bleeding; remove when no longer required

This visual aid will be posted at the room entrance for participants randomized to the intervention arm. Additionally, when laboratory orders and placed through the electronic health record, an electronic version of this aid will be sent once daily to the ordering provider in their secure inbox message.

Supplemental Figure 2. Best practice advisory for the intervention arm



This best practice advisory will open upon electronic order one-time per ordering provider per day throughout the duration of the index hospitalization.

Supplemental Content: IV iron administration details

Low molecular weight iron dextran will be administered by critical care nurses who have received training in iron administration in accordance with institutional medication administration protocols. A small test dose of 25 mg will be given over 5 minutes to ensure no symptoms of adverse reaction with continuous assessment by the bedside nurse, including monitoring of pulse oximetry, heart rate, blood pressure, and temperature and visual inspection of the patient for rashes or signs of physical and/or respiratory distress. Following the test dose, the remaining 975 mg dose will be administered via continuous IV infusion over 2 hours. At the discretion of the clinical team, patients deemed to be at high-risk for infusion reactions (e.g., inflammatory arthritis) may be given steroid premedication (e.g., 125 mg methylprednisolone). If a patient develops or is suspected of developing an infusion reaction, therapy will be immediately halted. All infusion reactions will be immediately reported to study personnel for accurate characterization and reporting. Those deemed to have a minor infusion reaction (i.e., rash in absence of hemodynamic or respiratory compromise) will be observed for 15 minutes for signs of clinical progression. If symptoms abate within 15 minutes, the infusion will be restarted at a lower rate. If the patient has persistent mild symptoms, recurrent symptoms, and/or urticaria, they will be treated with antihistamines (e.g., ranitidine 50 mg), in accordance with institutional policy, prior to restarting the infusion at a lower rate. If there is concern for a moderate infusion reaction or further symptom progression (e.g., hypotension, worsening rash), patients may also receive IV steroids (e.g., methylprednisolone 1-2 mg/kg) and/or intravenous crystalloids at discretion of ICU team. Symptoms should abate completely prior to re-challenging with IV iron, and an alternative iron formulation with comparable dosing will be considered. Should a severe reaction be observed (i.e., respiratory distress, anaphylaxis), the

patient will receive immediate treatment with IV epinephrine and additional cardiopulmonary support as dictated by the ICU treatment team. Patients without any apparent reaction to IV iron will be observed clinically for 1-hour post-infusion for the development of delayed reactions with blood pressure measurements at least every 15 minutes, continuous pulse oximetry, and telemetry. Those experiencing infusion reactions will be observed for longer times as dictated by the severity of the reaction. It is commonly thought that iron may predispose patients to bacterial infections; however, this has not been shown in multiple clinical trials in the critically ill. Out of an abundance of caution, we will exclude patients with uncontrolled sepsis, defined as <48 hours of appropriate antimicrobial therapy and/or lack of definitive source control. Additionally, as a long-term risk, repeated doses of iron administration, particularly to patients with iron storage disorders (i.e., hemochromatosis) or those requiring frequent and recurrent RBC transfusions, can culminate in iron overload. Patients with hemochromatosis or elevated iron stores (i.e., ferritin > 1000 ng/ml) will not be eligible to receive iron.

Supplemental Content: Consent Form

RESEARCH PARTICIPANT CONSENT AND PRIVACY AUTHORIZATION FORM

Study Title: The **P**ractical **A**nemia **B**undle for **S**us**T**ained **B**lood **R**ecovery (PABST-BR) Trial

IRB#: 21-006511

Principal Investigator: Matthew Warner, MD

Key Study Information

This section provides a brief summary of the study. It is important for you to understand why the research is being done and what it will involve before you decide. **Please take the time to read the entire consent form carefully and talk to a member of the research team before making your decision.** You should not sign this form if you have any questions that have not been answered.	
It's Your Choice	This is a research study. Being in this research study is your choice; you do not have to participate. If you decide to join, you can still stop at any time. You should only participate if you want to do so. You will not lose any services, benefits or rights you would normally have if you choose not to take part.
Research Purpose	The purpose of this research is to test a treatment plan to help reduce further anemia (a low blood count or hemoglobin level) and to promote hemoglobin and functional recovery in adults who have been in the intensive care unit (ICU). You have been asked to take part in this research because you are a patient in the ICU and have anemia.
What's Involved	Study participation involves either receiving standard of care, or, if in the intervention group, having measures put in place that aim to reduce blood loss from the frequent blood draws that occur while in the hospital, including fewer blood draws and lower volumes of blood removed. Also, if in the intervention group, you will receive either one or two drugs to help boost your blood hemoglobin level. Lab test results will direct whether you get one or both of these drugs. We will follow you throughout the hospital stay and you will return for two follow-up visits after hospital discharge, at 1 and 3 months. We will follow you up to 12 months after you are discharged from the hospital but you will not be contacted. This will be completed through review of your medical records.

Key Information	You have the choice to decline participation in this study and receive the standard of care for ICU patients. If you agree to participate you will be randomized as in a flip of a coin to either receive standard of care or be placed in the interventional study group. Both standard of care and the intervention subjects will have study lab samples drawn while in the hospital and at the follow up visits. If able, while in the hospital, the blood samples will be taken from a small tube you may have in a vein to avoid the stick of a needle. At the follow up visits it will require a single blood draw from a small needle in your vein. Pain, bruising, and infection are all risks of having blood drawn. The changes to blood draws used in the intervention group (i.e. fewer draws, lower volume draws) has no added risk to you. In very rare instances (less than 1%), the lab may not get enough blood to run an ordered lab test and a second blood draw may be needed. Subjects in the intervention group will receive an actual drug(s). There is no placebo used in this study. The drugs are both commonly used in clinical practice to help boost hemoglobin levels and treat anemia. Subjects identified at higher risk to using these drugs are already excluded from taking part in this trial. Iron Dextran: This drug is approved by the U.S. Food and Drug Administration (FDA) to treat anemia in patients with low iron stores. If you have low iron stores, this drug will be given to you once through a small tube you already have in your vein (IV) per standard hospital procedure by the trained ICU nurse caring for you. Risk that may be seen with this drug may include allergic reaction (less than 1%), non-allergic reaction such as muscle &/or joint pain and dizziness (less than 1%). If lab values show your iron levels are adequate, you will not get this drug. Erythropoietin (EPO): This drug encourages your body to produce more red blood cells. It is approved by the FDA for the treatment of anemia in those with kidney disease or recent chemotherapy, and it is also commonly used in critically ill patients with other types of anemia. It will be given once by injection into the subcutaneous (SQ) tissue of your body. Possible risks that may be seen with EPO include minor non-allergic reactions such as nausea, dizziness, high blood pressure, itching (less than 10%), and major rare reactions such as blood clots, high blood pressure, heart attack (less than 1%). Potential benefits of the study intervention include less blood taken for lab tests and higher hemoglobin levels. Past studies have shown that treatment

	with these drugs encourages hemoglobin recovery during critical illness and EPO has shown to reduce the need for blood transfusions. Long term benefits may show that those who get Iron or EPO could have improved hospital and post-hospital outcomes, including less fatigue, better physical function, and fewer hospitalizations.
Learn More	If you are interested in learning more about this study, read the rest of this form carefully. The information in this form will help you decide if you want to participate in this research or not. A member of our research team will talk with you about taking part in this study before you sign this form. If you have questions at any time, please ask us.

Making Your Decision

Taking part in research is your decision. Take your time to decide. Feel free to discuss the study with your family, friends, and healthcare provider before you make your decision. Taking part in this study is completely voluntary and you do not have to participate.

If you decide to take part in this research study, you will sign this consent form to show that you want to take part. We will give you either a printed or electronic copy of this form to keep. A copy of this form will be put in your medical record.

If you are signing this consent form for someone else, "you" in the consent form refers to the participant.

For purposes of this form, Mayo Clinic refers to Mayo Clinic in Rochester, Minnesota.

Contact Information

If you have questions about …	You can contact …
▪ Study tests and procedures ▪ Materials you receive ▪ Research-related appointments ▪ Research-related concern or complaint ▪ Research-related injuries or emergencies ▪ Withdrawing from the research study	**Principal Investigator:** Matthew Warner, MD Phone: 507-422-XXXX **Study Team Contact:** Matthew Johnson, RN Phone: 507-422-XXXX **Institution Name and Address:** Mayo Clinic 200 First Street SW Rochester, MN 55905

If you have questions about …	You can contact …
▪ Rights of a research participant	**Mayo Clinic Institutional Review Board (IRB)** **Phone:** (507) 266-XXXX **Toll-Free:** (866) 273-XXXX
▪ Rights of a research participant ▪ Any research-related concern or complaint ▪ Use of your Protected Health Information ▪ Stopping your authorization to use your Protected Health Information ▪ Withdrawing from the research study	**Research Subject Advocate (RSA)** **(The RSA is independent of the Study Team) Phone:** (507) 266-XXXX **Toll-Free:** (866) 273-XXXX **E-mail:** researchsubjectadvocate@mayo.edu
▪ Billing or insurance related to this research study	**Patient Account Services** **Toll-Free:** (844) 217-XXXX

Other Information:

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Why are you being asked to take part in this research study?

You are being asked to take part in this research study because you are in an ICU and have anemia (a low blood count or hemoglobin level). The plan is to have about 100 people take part in this study at Mayo Clinic.

Why is this research study being done?

The purpose of this study is to test a treatment plan to help reduce further anemia (a low blood count or hemoglobin level) and to promote hemoglobin and functional recovery in adults who have been in the ICU.

Information you should know

Who is Funding the Study? The National Heart, Lung, and Blood Institute (NHLBI) is funding the study.

Information Regarding Conflict of Interest: Your healthcare provider may be referring you to this research study. If your healthcare provider is also an investigator on this study, there is the chance that his or her responsibilities for the study could influence his or her recommendation for your

participation. If you prefer, your healthcare provider will be happy to refer you to another investigator on the research study team for you to decide if you want to participate in the study and to see you for the research study activities while you are in the study.

How long will you be in this research study?

You will actively be in the study until you complete the 3-month follow-up visit after hospital discharge. To complete research aims the study team will review your medical record at 12 months after hospital discharge. You will not be contacted for this.

What will happen to you while you are in this research study?

If you are eligible for the study, we will assign you by chance (like a coin toss) to the control group (standard of care) or the intervention group. You and the Principal Investigator can't choose your study group. You will have an equal chance of being assigned to the intervention group. You will be told which group you were randomly assigned.

All study participants will have the following blood tests:

After you consent to the study: Anemia labs (hemoglobin, ferritin, transferrin saturation), research samples for future biomarker testing and a pregnancy test if needed.

At hospital discharge: Anemia labs (hemoglobin, ferritin, transferrin saturation).

At the 1 and 3 months follow up visits: Anemia labs (hemoglobin, ferritin, transferrin saturation) and research samples for future biomarker testing.

About 5 teaspoons of blood will be drawn from you after you consent to be in the study, at hospital discharge and at the 1 and 3 month follow up visits. Some of these blood tests are part of regular clinical care and may be done even if you do not join the study. If you have had some of them recently, they may not need to be repeated. This will be up to the Principal Investigator.

Tests done only for research purposes are not meant to provide clinical information or help care for you. The results are only important for research. Therefore, the results of tests done with your information and samples will not be provided to you. In the rare event that a finding might affect the health of you or your family, we will contact you and you can choose whether to receive or refuse the information. If you decide to follow up and further medical testing or care is needed, the costs will be billed to you or your insurance.

All study participants will be asked to fill out questionnaires about your general health and well-being and quality of life. We hope that you will answer all of the questions, but you can skip any questions you don't want to answer. The questionnaires occur at enrollment, hospital discharge and at the 1 and 3 months follow up visits. They vary in type of questions and length depending on which visit but in general will take between 5 and 25 minutes to complete.

In order to measure your functional recovery, you will be asked to do a 6-minute walk at the 1 and 3 months follow up visit. These visits take place in an outpatient setting at Mayo Rochester.

If in the intervention group, you will have measures put in place to decrease the amount of blood taken for lab testing while in the hospital. These measures include removing less blood with each blood draw and having the blood draw team use a closed-loop system attached to the tube in your vein to reduce the amount of blood loss at the time of blood draws. Measures also include asking the team caring for you to be aware of the frequency and amount of blood draws they order.

Intervention group subjects will also receive a one-time dose of one or two drugs, Iron Dextran and/or Erythropoietin (EPO). There is no placebo used in this study and both drugs are used clinically to treat anemia. These drugs will be given to you by the ICU nurse taking care of you according to standard hospital administration guidelines. The study doctors will review the lab results to determine whether you receive Iron, EPO or both.

Also, the study team will be reviewing your electronic health record to note your demographics, medical history, vital signs, fluid balance, creatinine, platelets and white blood cell count, red blood cell transfusions you may have received, medications you are taking, total daily number of blood draws you have while in the hospital and adverse events. The study team will review your health record at 12 months to identify any hospital readmissions and mortality status.

What are the possible risks or discomforts from being in this research study?

The risks of drawing blood include pain, bruising, lightheadedness, and/or fainting, or rarely, infection at the site of the needle stick. When able, the blood samples will be taken from a tube you already have in your arm.

As with any medication, allergic reactions are possible. Subjects in the intervention group will receive one or both drugs, depending on the results of your lab tests.

Iron Dextran: If the study doctors decide you would benefit from Iron Dextran, it will be given one time through an IV by your ICU nurse who will observe for any reaction. Risks that may be seen include allergic reaction (occurs in less than 1% of patients), non-allergic reaction such as muscle pain, joint pain and dizziness (occurs in less than 1% of patients).

Erythropoietin (EPO): If the study doctors decide you would benefit from Erythropoietin (EPO), it will be given one time by subcutaneous injection by your ICU nurse who will observe for any reaction. Risks that may be seen include minor non-allergic reactions such as nausea, dizziness, high blood pressure and itching (occurs in less than 10% of patients) and major rare reactions such as blood clots, high blood pressure, heart attack (occurs in less than 1% of patients).

As with all research, there is a chance that confidentiality could be compromised; however, we take precautions to minimize this risk.

Are there reasons you might leave this research study early?

You may decide to stop at any time. You should tell the Principal Investigator if you decide to stop and you will be advised whether any additional tests may need to be done for your safety.

In addition, the Principal Investigator or Mayo Clinic may stop you from taking part in this study at any time:

- If it is in your best interest,
- If you don't follow the study procedures,
- If the study is stopped.

If you leave this research study early, or are withdrawn from the study, no more information about you will be collected; however, information already collected about you in the study may continue to be used.

We will tell you about any new information that may affect your willingness to stay in the research study.

What if you are injured from your participation in this research study?

Where to get help:

If you think you have suffered a research-related injury, you should promptly notify the Principal Investigator listed in the Contact Information at the beginning of this form. Mayo Clinic will offer care for research-related injuries, including first aid, emergency treatment and follow-up care as needed.

Who will pay for the treatment of research related injuries?

Care for such research-related injuries will be billed in the ordinary manner, to you or your insurance. You will be responsible for all treatment costs not covered by your insurance, including deductibles, co-payments and coinsurance.

What are the possible benefits from being in this research study?

This study may not make your health better. If you receive the intervention, your anemia may be slowed from worsening. It is also possible your hemoglobin and physical recovery after hospitalization may improve more quickly than those receiving standard of care.

What alternative do you have if you choose not to participate in this research study?

You do not have to be in this study. Most patients with your condition (i.e. anemia) do not receive any therapies to prevent anemia during their hospital stay. Some patients are given blood transfusion as treatment for anemia, and this option would remain available to you whether or not you are in the study. Even if you are not in the study, you may be eligible to receive the study intervention drugs (i.e. iron, EPO) if offered by your clinician, though this is not common. Talk to the Principal Investigator or your doctor if you have any questions about any of these treatments or procedures.

What tests or procedures will you need to pay for if you take part in this research study?

You won't need to pay for tests and procedures which are done just for this research study. These tests and procedures are:

- Hemoglobin and iron levels done at baseline, hospital discharge and at 1 & 3 months
- Research samples at baseline and at 1 & 3 months
- Pregnancy test if needed
- Study questionnaires

If your doctor orders the following tests while you are in the hospital as part of standard of care, we will use the results for this research study, and they will be billed to your insurance. These tests are: Platelets, WBC, Creatinine, hemoglobin, MCV, RDW, ferritin, iron, transferrin saturation, reticulocyte hemoglobin, absolute reticulocyte count.

However, you and/or your insurance will need to pay for all other tests and procedures that you would have as part of your clinical care, including co-payments and deductibles.

The study drugs, EPO &/or Iron Dextran and their administration will be given to you at no cost. You and/or your insurance might have to pay for other drugs or treatments given to help control side effects.

If you have billing or insurance questions call Patient Account Services at the telephone number provided in the Contact Information section of this form.

Will you be paid for taking part in this research study?

You will receive a $25 payment through Mayo Clinic's Research Participant Payment Application for each follow up visit you complete at 1 and 3 months. At each visit, you will receive a 4-hour parking voucher to be used in a Mayo Clinic parking facility.

Payment for participation in research is considered taxable income and reportable to the Internal Revenue Service (IRS). Accounts Payable at Mayo Clinic will be given your name, address and Social Security number in order to issue a check for your study participation. If you receive research payments totaling $600 or more in a calendar year, a tax Form 1099 will be sent to you. For Mayo Clinic employees, research payments are included in your paycheck with applicable taxes withheld and reported on your Form W2 after calendar year-end.

Will your information or samples be used for future research?

Unless you give your permission below, your information or samples collected for this study will not be used or shared for future research, even if the identifiable information such as your name, Mayo Clinic number or date of birth is removed.

We would like to keep your information and samples for future research. You can still take part in this current study even if you don't want your information or samples used for future research.

Researchers at Mayo Clinic who aren't involved with this study may ask to use your information and/or samples for future research. Researchers at other institutions may also ask for a part of your information and/or samples for future studies. Unless you indicate otherwise, the future research may be on any topic. No direct benefits to you are expected from the future research. Your information and/or samples will only be shared consistent with your consent, and with all applicable laws and regulations.

If you approve release of your information and/or samples by checking 'yes' below, Mayo may send the information and/or samples to researchers who request them, but Mayo will not send your name, address, phone number, social security number, or any other identifying information with the information and/or samples. Your information and/or samples may be sent with a code, and only the researchers for this study at Mayo Clinic would be able to link the code to you.

Some future studies may examine your DNA, the genetic information you inherited from your parents (genetic testing). If there are findings which may be useful for your health care, the researchers may contact Mayo Clinic, so Mayo Clinic can give you the option of learning the results. You would be given general information on the potential risks, benefits, and costs of choosing to learn about the findings.

To support future research, de-identified genetic information may be placed in databases accessible by the internet. Some of the information may be available to anyone using the internet, and some will be released only to approved researchers. Combined study information (including genomic summary results) may be published, but the information will not identify you.

Even though information traditionally used to identify you will not be shared, people may develop ways in the future to allow someone to link your genetic information back to you. For this reason, confidentiality cannot be guaranteed. It is also possible that reidentified information could be used in discriminating ways, and there could be additional unknown risks. We will make every effort to protect your confidentiality.

Privacy protections given by the Certificate of Confidentiality for this study do not apply to combined study results; however, they do apply to your individual information. (See separate section for information about the Certificate of Confidentiality.)

Please read the following statements and mark your choices:

1. I permit my information and samples to be stored and used in future research of anemia at Mayo Clinic:

☐ Yes ☐ No Please initial here: _____Date: _____

2. I permit my information and samples to be stored and used in future research at Mayo Clinic to learn about, prevent, or treat any other health problems:

☐ Yes ☐ No Please initial here: _____Date: _____

3. I permit Mayo Clinic to give my information and samples to researchers at other institutions:

☐ Yes ☐ No Please initial here: _____Date: _____

You may withdraw your consent for future use of your information and/or samples at any time, by writing to the Principal Investigator at the address provided in the "Contact Information" section of this consent form.

Your information and/or samples would be removed from any repository where they are stored, if possible. Information and/or samples already distributed for research use will not be retrieved.

How will your privacy and the confidentiality of your records be protected?

Mayo Clinic is committed to protecting the confidentiality of information obtained about you in connection with this research study.

Research data will be entered in and maintained using a secure database that is a web-based application, HIPAA-compliant and secure. Data are housed behind the Mayo Clinic firewall and password-protected user access is restricted to study staff. Data security and confidentiality will be assured by using coded subject IDs with the locked master-file linking these IDs to the subject name and identifiers held by Dr. Warner and his staff.

We have obtained a **Certificate of Confidentiality** from the Department of Health and Human Services (DHSS). The Certificate is designed to prevent us from being forced to disclose identifying information for use in any federal, state, or local civil, criminal, administrative, legislative, or other court proceeding, even if faced with a court subpoena. You should understand, however, that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. We may not withhold information if you give your insurer or employer or a law enforcement agency permission to receive information about your participation in this research. This means that you and your family must also actively protect your own privacy.

The Certificate does not prevent us from taking steps, including reporting to authorities, to prevent serious harm to yourself or others. Such disclosures will be made as described below.

The research team may share your information with:

- DHHS, to complete federal responsibilities for audit or evaluation of this research;
- Public health agencies, to complete public health reporting requirements;
- Mayo Clinic representatives, to complete responsibilities for oversight of this study;
- Your primary care physician if a medical condition that needs urgent attention is discovered;
- Appropriate authorities to the extent necessary to prevent serious harm to yourself or others.

During this research, information about your health will be collected. Under Federal law called the Privacy Rule, health information is private. However, there are exceptions to this rule, and you should know who may be able to see, use and share your health information for research and why they may need to do so. Information about you and your health cannot be used in this research study without your written permission. If you sign this form, it will provide that permission (or "authorization") to Mayo Clinic.

Your health information may be collected from:

- Past, present and future medical records.
- Research procedures, including research office visits, tests, interviews and questionnaires.

Your health information will be used and/or given to others to:

- Do the research.
- Report the results.
- See if the research was conducted following the approved study plan, and applicable rules and regulations.

Your health information may be used and shared with:

- Mayo Clinic research staff involved in this study.
- Other Mayo Clinic staff involved in your clinical care.

- The Mayo Clinic Institutional Review Board that oversees the research.
- Federal and State agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health and other United States agencies) or government agencies in other countries that oversee or review research.

How your information may be shared with others:

While taking part in this study, you will be assigned a code that is unique to you but does not include information that directly identifies you. This code will be used if your study information is sent outside of Mayo Clinic. The groups or individuals who receive your coded information will use it only for the purposes described in this consent form.

If the results of this study are made public (for example, through scientific meetings, reports or media), information that identifies you will not be used.

In addition, individuals involved in study oversight and not employed by Mayo Clinic may be allowed to review your health information included in past, present, and future medical and/or research records. This review may be done on-site at Mayo Clinic or remotely (from an off-site location). These records contain information that directly identifies you. However, the individuals will not be allowed to record, print, or copy (using paper, digital, photographic or other methods), or remove your identifying information from Mayo Clinic.

Is your health information protected after it has been shared with others?

Mayo Clinic asks anyone who receives your health information from us to protect your privacy; however, once your information is shared outside Mayo Clinic, we cannot promise that it will remain private and it may no longer be protected by the Privacy Rule.

Your Rights and Permissions

Participation in this study is completely voluntary. You have the right not to participate at all. Even if you decide to be part of the study now, you may change your mind and stop at any time. You do not have to sign this form, but if you do not, you cannot take part in this research study.

Deciding not to participate or choosing to leave the study will not result in any penalty. Saying 'no' will not harm your relationship with your own doctors or with Mayo Clinic.

If you cancel your permission for Mayo Clinic to use or share your health information, your participation in this study will end and no more information about you will be collected; however, information already collected about you in the study may continue to be used.

You can cancel your permission for Mayo Clinic to use or share your health information at any time by sending a letter to the address below:

Mayo Clinic
Office for Human Research Protection
ATTN: Notice of Revocation of Authorization
201 Building 4-60
200 1st Street SW
Rochester, MN 55905

Alternatively, you may cancel your permission by emailing the Mayo Clinic Research Subject Advocate at: researchsubjectadvocate@mayo.edu.

Please be sure to include in your letter or email:

- The name of the Principal Investigator,
- The study IRB number and /or study name, and

- Your contact information.

Your permission for Mayo Clinic to use and share your health information lasts forever, unless you cancel it.

Enrollment and Permission Signatures

Your signature documents your permission to take part in this research.

	/ /	: AM/PM
Printed Name	Date	Time

_____

Signature

Signature of Legally Authorized Representative for Adult Participant

- I give permission for the participant to take part in this research study and agree to allow his/her health information to be used and shared as described above.

AM/PM

Signature	Printed Name	Relationship to Participant	Date	Time

Person Obtaining Consent

- I have explained the research study to the participant.
- I have answered all questions about this research study to the best of my ability.

	/ /	: AM/PM
Printed Name	Date	Time

_____

Signature