Intravenous Iron Isomaltoside versus Iron Sucrose for Treatment of Iron Deficiency in Pregnancy

Inclusion/Exclusion Criteria Form REB # 21-64 HC6-24-c260086

Participant ID: (Code Supplied to Participant) XXX	Date: MMM/DD/YYYY	Obstetrical Care Provider (Please Print):

Inclusion Criteria

Patient must meet ALL of the following criteria to be eligible for enrolment as a study participant:

	Yes	No
• Pregnant woman at GA ≥ 13 weeks but less than or equal to 35 weeks 6 days		
• Age ≥ 18 years		
• Iron/TIBC (TSAT) <20%		
• Serum ferritin <30ug/L		
• Hb <110 g/L		
• Willing to participate and attend all planned appointments, follow-up visits (at baseline, during infusion, during delivery, and six weeks postpartum) and planned blood work.		

Exclusion Criteria

If patient meets *any* of these criteria, patient is not eligible for enrolment as a study participant:

	Yes	No
• Pregnancy with GA <13 weeks		
• Does not meet defining criteria for IDA [Iron/TIBC (TSAT) < 20%, Serum Ferritin <30ug/L, Hb <110g/L]		
• Age <18 years		
• History of anemia caused by thalassemia or others haematologic disorder other than iron deficiency anemia		
• Known serious hypersensitivity to other parental iron products		
• History of multiple allergies (drug, environmental, food)		
• Iron overload or disturbances in utilization of iron (example: haemochromatosis and haemosiderosis)		
• Decompensated liver cirrhosis or active hepatitis		

	Yes	No
• Active acute infection or chronic infection		
• Treated with IV iron products or blood transfusion within 4 weeks prior to inclusion		
• Participant in any other interventional/concurrent trial		
• Multiple gestation pregnancy (twins, triplets)		
Significant comorbidities: • Asthma/Lung Disease		
• Heart Disease		
• Kidney Disease		
• Rheumatologic disease		
• Cancer		
• Known hypersensitivity to iron sucrose or iron isomaltoside or any of its excipients		
• Known allergies or sensitivities to oral iron		

Fax form to: 306-766-3466
Email form to: patientbloodmanagement@saskhealthauthority.ca (confidential email)

May we contact you if more information needed? Yes □ No □
Best contact information: Telephone: _____ Email: _____

Form Completed by: _____ Date: _____

Clinical Trial Coordinator Only:

Clinical Trial Coordinator Signature: _____ Date:_____		
Copy of signed ICF on file	Date verified:	Initials:
Copy of Inclusion/Exclusion criteria form on file	Date verified:	Initials:
Patient education documents sent to patient	Date verified:	Initials:
Patient information placed in confidential database	Date verified:	Initials:
Confirmation of enrolled patient sent to obstetrical care provider	Date verified:	Initials:
Copy of completed PPO sent to Infusion Clinic and to MBU	Date verified:	Initials: