

Metabolic Control RCT

Enrollment Form

[tblPEnrollmentHx](#)

ENROLLMENT HISTORY	
VisitDt	1. Enrollment Visit Date: ____ / ____ / ____ mm/dd/yy
InvID	2. Study ID of Investigator ____--____

DIAGNOSIS INFORMATION	
DiagDt DiagHr DiagMin DiagAMPM	1. Date and Time of Diagnosis of Diabetes: ____ / ____ / ____ mm/dd/yy ____ : ____ <input type="checkbox"/> AM <input type="checkbox"/> PM
SubjHosp	2. Was the subject hospitalized? <input type="checkbox"/> Yes <input type="checkbox"/> No
DKA	3. Was the subject in DKA? <input type="checkbox"/> Yes <input type="checkbox"/> No
IvIns	4. Was insulin given by IV drip? <input type="checkbox"/> Yes <input type="checkbox"/> No
InitGluc InitGlucNA	5. Initial glucose level: _____ <input type="checkbox"/> Not Available
CO2Diag CO2DiagNA	6. CO2 at time of diagnosis: _____ <input type="checkbox"/> Not Available
PHDiag PHDiagNA	7. pH at time of diagnosis: _____ <input type="checkbox"/> Not Available
KetoneDiagNA KetoneDiagSer KetoneDiagSerUnits KetoneDiagUrine	8. Ketone result at time of diagnosis: <input type="checkbox"/> Not Available 8a. Serum: _____ units dropdown 8b. Urine: <input type="checkbox"/> Negative <input type="checkbox"/> Trace <input type="checkbox"/> Small <input type="checkbox"/> Medium <input type="checkbox"/> Large <input type="checkbox"/> Extra Large

ELIGIBILITY	
<p>The following criteria must be met for the subject to be eligible for the study:</p> <ol style="list-style-type: none">1. If participant is female with reproductive potential, willing to avoid pregnancy and pregnancy test negative.2. Willing to accept randomization to either the intensive diabetes management group or the standard care group.3. Willing to complete the planned 2 years of follow-up.4. Able to electronically transmit data monthly (a PC based computer is required; Mac not acceptable)5. Investigator believes that the participant (and parent/guardian for children) understands and agrees to comply with the study protocol and is capable of undertaking all necessary testing.6. Subject does not have any of the following:<ul style="list-style-type: none">◆ Currently pregnant or lactating, or anticipate getting pregnant in the next one year.◆ Currently anemic (based on hematocrit level obtained for screening).◆ Chronic use of systemic steroids or other noninsulin pharmaceuticals that might affect	

<p>SubjEligible</p> <p>CRCAAdminWin</p>	<p>glycemic control or the presence of a disease that is likely to be treated with such medications during the first two years of the study.</p> <ul style="list-style-type: none"> ◆ Complicating medical issues that might interfere with study conduct ◆ Inpatient psychiatric treatment in the past 6 months (if the participant is a minor, for either the participant or the participant's primary care giver). ◆ Currently participating in another type 1 diabetes treatment study, including an intervention trial for treatment of diabetic ketoacidosis. <p>1. The subject meets all eligibility criteria above and is a good candidate for the study. <input type="checkbox"/> YES <input type="checkbox"/> NO</p> <p>2. If subject is randomized to the Intense Group, subject is able to be admitted to the CRC within 7 days of diagnosis. <input type="checkbox"/> YES <input type="checkbox"/> NO</p>
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DEMOGRAPHIC INFORMATION	
Gender	1. Gender: <input type="checkbox"/> Male <input type="checkbox"/> Female
Ethnicity	2. Ethnicity: <input type="checkbox"/> Hispanic or Latino <input type="checkbox"/> Not Hispanic or Latino <input type="checkbox"/> Unknown/not reported
Race	3. Race: <input type="checkbox"/> White <input type="checkbox"/> Black/African-American <input type="checkbox"/> Native Hawaiian/Other Pacific Islander <input type="checkbox"/> Asian <input type="checkbox"/> American Indian/Alaskan Native <input type="checkbox"/> More than one race <input type="checkbox"/> Unknown/not reported
RaceDs	
<p>If more than one race selected please specify:</p> <p>_____</p>	

SOCIOECONOMIC INFORMATION	
EduCareGvrP	1. Please select the highest level of education completed by the primary caregiver(s):
EduCareGvrPEdu	1a. Caregiver: Mother , Father, Grandmother, GrandFather, Aunt, Uncle, Older Sibling, Subject, Spouse
EduCareGvrS	1b. Caregiver: Mother, Father, Subject Spouse
EduCareGvrSEdu	i. Education: <4 4 5 6 7 8 9 10 11 12 AA BS/BA MS/MA Professional Degree (eg MD)

PHYSICAL EXAMINATION	
PhExamComp	<input type="checkbox"/> A physical examination was completed
Weight	1. Weight: _____ . _____ kg
Height	2. Height: _____ . _____ cm

COMMENTS [FormCmts](#)
