

FORM NO. CNA006								
Acrostic Identifier:								
Study ID:								
Date source form completed:/								
Physical Exam - Day of Injection								
Date of Exam:/								
☐ Informed consent was revised since study start date								
Date patient reconsented:// Consent version:								
	Vital	Signs			NYHA	Class:	С	CS Class:
Weight:		pounds						I
Temperature:	°F	□oral	auricle					II
Respirations:	breat	ns/minute			<u> </u>	I		III
Heart rate:	be	ats/minute			□ I\	/		IV
Blood Pressure:	/ SBP	— — — DBP	mmHg (sup	ine)	□ N/A □ N		N/A	
Review of Systems:	OBI	DDI						
Have changes occurred	since previo	us visit?	Yes No	☐ If no, ta	able is compl	ete.		
<u>Organs</u>		<u>Normal</u>	Abnormal	Not Examined	<u>Describe</u>			
Skin								
HEENT								
Lungs								
CV								
Abdomen								
Lymph Nodes								
Musculoskeletal								
Neurological								
Other:								
Questions:								
Has the patient experien (If yes, complete AE form	•	adverse eve	ents?		Yes 🗆 1	No 🗆		
Have there been any significant changes in physical findings since last visit? (If yes, please explain in comments)								
Have there been any changes to medications?  (If yes, update medication form)  Yes No								



FORM NO. CNA006			
Acrostic Identifier:			
Study ID:			
Date source form co	mpleted:/		
	Physical Exam - Day of Ir	njection	
Questions:			
	le assessment completed? (If not done, or if cit, please explain in comments)	Yes No	No evidence of deficit   Evidence of deficit
Core Lab? (If no, please		Yes No	N/A 🔲
	ast transthoracic Echo performed immediately ile in the coronary angiography recovery area to	Yes 🗌 No 🔲	Normal $\square$
determine the presence			Abnormal
Was the routine no contrast Echo completed 4-6 hours post procedure		Yes No	Normal
Lab? (If not done, or if re	sult abnormal, please explain in comments)		Abnormal
one 10 ml venous blood drawn to ship to the biore (If no, please explain in t	•	Yes No	
Has there been a change (If yes, please update me	e in nitrate usage since last visit? edication form)	Yes No	N/A 🗌
*Please remember to u	pdate medication form with inter-visit changes	to medications	
Comments:			
Entered to eCRF	Initials		



FORM NO. CNA029	
Acrostic Identifier:	
Study ID:	
Date source form completed: _	/
В	one Marrow Aspiration
Procedure Date:	
Procedure Venue:	☐ Patient Room ☐ Cath Lab ☐ OR
Time initial aspiration start:	:
Time aspiration complete:	
Total amount aspirated:	ml
Did the patient experience an the procedure? (If yes, comple	YASIINAII
Were concomitant medications (If yes, add to medication form	YASI INO I I
Comments:	
Entered to eCRF	Initials



FORM NO. CNA03	1							
Acrostic Identifier:								
Study ID:								
Date source form c	ompleted:/							
Vital Signs Pre-Pr	ocedure (Pre-Study Product Injection)							
Date:/	/ Time: :							
Temperature:	°F							
Respirations:	breaths/min							
Heart rate:	beats/min							
Blood Pressure:	/ mmHg (supine) SBP DBP							
Study Product Inje	ection Period							
Procedure	Start Date:/							
Mapping Procedure	Start Time: : Stop Time: :							
Injection Procedure	Start Time:: Stop Time::							
Nitroglycerin given?	No  Yes  Amount: mcg (IC)							
Heparin given?	No Yes Amount: units							



FORM NO	CNA03	1						
Acrostic I		•						
Study ID:								
	Study ID:							
Date soul	rce form c	ompleted: _	//_					
Mapping	/ Injection	n Informati	ion					
Number of	Segments	of testing d	evice?	□ 12	□17			
Mapping Segment	UPV	LLS	# Injections / segment		Diagram of Mapping Segments  Anterior  LAD			
1	mV	%		17 segment	1 I			
2	mV	%		(TX)	Antero-			
3	mV	%			septal 2 8 13 12 6 lateral			
4	mV	%			14 17 16			
5	mV	%			9 15 11			
6	mV	%			3 10 5			
7	mV	%			Infero- septal 4 lateral			
8	mV	%			PDA Inferior			
9	mV	%		12 segment (CL, FL, MN,				
10	mV	%		VN)	LAD Anterior			
11	mV	%			Antero-			
12	mV	%			septal 1 lateral			
13	mV	%			5 (9 12			
14	mV	%			11 7			
15	mV	%						
16	mV	%			Infero- septal Infero- lateral			
17	mV	%			8			
Total Map	pping Poin	ts:	Sum of Inject	tion Points:	PDA Inferior			



FORM N	O. CNA03	1							
Acrostic I	dentifier:								
Study ID:									
Date soul	Date source form completed://								
Injection Information									
Injection Points	Segment Number	Loop Stability	ST Elevation	UPV	Presence of PVCs	Volume of Injection	Arrhythmia Present	Not Done	
1		mm	Yes 🗌 No 🔲	mV	Yes 🗌 No 🔲	ml	Yes 🗌 No 🔲		
2		mm	Yes 🗌 No 🔲	mV	Yes 🗌 No 🔲	ml	Yes 🗌 No 🔲		
3		mm	Yes 🗌 No 🔲	mV	Yes 🗌 No 🔲	ml	Yes 🗌 No 🔲		
4		mm	Yes 🗌 No 🔲	mV	Yes 🗌 No 🔲	ml	Yes 🗌 No 🔲		
5		mm	Yes 🗌 No 🔲	mV	Yes 🗌 No 🔲	ml	Yes 🗌 No 🔲		
6		mm	Yes 🗌 No 🔲	mV	Yes 🗌 No 🔲	ml	Yes 🗌 No 🔲		
7		mm	Yes 🗌 No 🔲	mV	Yes 🗌 No 🔲	ml	Yes 🗆 No 🗀		
8		mm	Yes 🗌 No 🔲	mV	Yes 🗌 No 🔲	ml	Yes 🗌 No 🔲		
9		mm	Yes $\square$ No $\square$	mV	Yes 🗆 No 🗆	ml	Yes $\square$ No $\square$		
10		mm	Yes $\square$ No $\square$	mV	Yes 🗆 No 🗆	ml	Yes $\square$ No $\square$		
11		mm	Yes 🗆 No 🗀	mV	Yes 🗆 No 🗆	ml	Yes 🗆 No 🗀		
12		mm	Yes 🗌 No 🔲	mV	Yes 🗌 No 🔲	ml	Yes 🗌 No 🔲		
13		mm	Yes 🗌 No 🔲	mV	Yes 🗌 No 🔲	ml	Yes 🗌 No 🔲		
14		mm	Yes 🗌 No 🔲	mV	Yes 🗌 No 🔲	ml	Yes 🗌 No 🔲		
15		mm	Yes 🗌 No 🔲	mV	Yes 🗌 No 🔲	ml	Yes 🗌 No 🔲		
16		mm	Yes 🗌 No 🔲	mV	Yes 🗌 No 🔲	ml	Yes 🗌 No 🔲		
17		mm	Yes 🗌 No 🔲	mV	Yes 🗌 No 🔲	ml	Yes 🗆 No 🗀		
18		mm	Yes 🗌 No 🔲	mV	Yes 🗌 No 🔲	ml	Yes 🗆 No 🗀		
19		mm	Yes 🗌 No 🔲	mV	Yes 🗌 No 🔲	ml	Yes 🗌 No 🔲		
20		mm	Yes 🗌 No 🔲	mV	Yes 🗌 No 🔲	ml	Yes 🗌 No 🔲		
Total Inje	ctions:		Total Volume	):				_	



Entered to eCRF

Initials \_\_\_\_\_

FORM NO. CNA031							
Acrostic Identifier:							
Study ID:							
Date source form c	ompleted:/						
Vital Signs Post-Procedure (Post-Study Product Injection)							
Date:/	/ Time:::						
Temperature:	°F						
Respirations:	breaths/minute						
Heart rate:	beats/minute						
Blood Pressure:	——— /——— mmHg (supine) SBP DBP						
Questions							
1. Was there any d (If yes, please expl	ifficulty with mapping? ain in Comments)	Yes 🗌	No 🗌				
2. Did the patient e (If yes, complete Al	xperience an adverse event during mapping? E or SAE form)	Yes 🗌	No 🗌				
3. Were all 15 inject (If no, please expla	•	Yes 🗌	No 🗌				
4. Was the injection procedure prematurely stopped due to any reason listed in Section 7.6 of the Protocol?  (If yes, complete AE or SAE, and/or UP form)							
5. Was the procedu	ure restarted?	Yes 🗌	No 🗌	N/A 🗌			
6. Did the patient experience an adverse event during the injection procedure? (If yes, complete AE or SAE form)  Yes □ No □							
7. Were concomita (If yes, add to Medi	nt medications given? cation form)	Yes 🗌	No 🗌				
Comments:							

#### CCTRN

#### **Cardiovascular Cell Therapy Research Network**

**FOCUS Protocol Workbook** 

FORM NO. CNA031
Acrostic Identifier:
Study ID:
Date source form completed:/

#### 7.6 Guidance for NOGA Catheter Usage (Per protocol version date: 11/5/08)

If any of the following symptoms occur either during LV mapping with the NOGA XP System or during endocardial injections with the MyoStar Injection Catheter, they could indicate a serious clinical deterioration. If any of the following events / symptoms occur, the procedure should be temporarily halted and the patient should be reevaluated for suitability to continue with the treatment under investigation: product administration should be discontinued.

- persistent complaints of chest pain;
- complains of cardiac pain associated with injections;
- persistent hypotension;
- complaints of shortness of breath;
- ICD shocks to stop ventricular tachycardia (VT);
- DC cardioversion or defibrillation for VT;
- there is any question as to the location of the catheter tip in relation to vasculature or the LV;
- any unanticipated change in level of consciousness or neurological status.

#### The procedure will be terminated in the event of:

- sustained hypotension not responsive to fluid administration;
- clinical signs and symptoms indicating acute coronary syndrome;
- clinical signs and symptoms indicating a cerebrovascular accident;
- cardiac tamponade is strongly suspected or confirmed;
- hemipericardium requiring pericardiocentesis
- two episodes of sustained ventricular tachycardia requiring cardioversion or administration of an antiarrhythmic;
  - the patient experiences one episode of ventricular fibrillation (VF);
- identification of thrombus in the LV or the Aorta that was not previously present on echo or left ventriculogram;
  - an aortic dissection is suspected or confirmed.;
  - cardiac perforation;
  - excessive bleeding from the bone marrow harvest site;
  - fever of 99.4 degrees or higher;
  - hemodynamically unstable.



FORM NO. CNA023							
Acrostic Identifier:							
Study ID:							
Date source form completed:/							
Holter Data Form	n - Day of Injection						
Date procedure started://	Predominant Rhythm: (mutually exclusive)						
Total recording time:::	☐ Sinus Rhythm ☐ Junctional Rhythm						
General:	☐ Paced Rhythm ☐ Ectopic Atrial Rhythm						
Total beats/QRS Complexes: beats	Atrial Flutter / Fibrillation						
Paced beats: beats	Heart Rates:						
Pauses/Longest RR Interval (> 2 secs):	Minimum:beats/min. @:						
Longest pause was seconds @:	Average:beats/min.						
Total number of pauses:	Maximum:beats/min. @ :						
Ventricular Arrhythmia Summary:	Supraventricular Arrhythmia Summary:						
Single/PVC: beats	Single/PAC: beats						
Couplets:	Couplets:						
Total number of NSVT Runs (≥ 3 beats)	Total number of SVT Runs						
Number of beats in longest NSVT run	Number of beats in longest SVT run						
Total number of sustained ventricular tachycardia runs	Intermittent Atrial Fibrillation / Atrial Flutter:						
(≥ 30 secs)	☐ Yes ☐ No						
	If yes, total no. of episodes						
	If yes, min.secs (duration of longest						
	episode)						
AV Block: (Choose all that apply)							
Transient AV block, 2nd degree-Mobitz type 1 (Wenkebac							
<u> </u>	ation of longest episode (secs)						
☐ Transient AV block, 2nd degree-Mobitz type 2	N/A						
total no. of episodes duration of longest episode (secs)							
Transient AV block, 3rd degree N/A							
	ation of longest episode (secs)						
Comments:							
PI Signature:							
Entered to eCRF Initials							



FORM NO. CNA024	
Acrostic Identifier:	
Study ID:	
Date source form completed://	
ECG - Day of Injection	
Date of Procedure:/	
PR interval: 0 sec QRS interval: 0 sec QT interval:	0 sec HR: bpm
☐ ECG NORMAL ☐ ECG NOT NORMAL	
Note: If you select "ECG NORMAL", you are done with this form.	
Rhythm: (Check all that apply)	
normal sinus rhythm ventricular de	emand pacemaker (VVI)
sinus arrhythmia atrial pacema	aker
sinus bradycardia (<60 bpm) dual chamber	r pacemaker (DDD)
sinus tachycardia (>100 bpm) wandering pa	acemaker
atrial fibrillation accelerated in	dioventricular rhythm
atrial flutter atrial prematu	ure complexes
multifocal atrial tachycardia ventricular pro	remature complexes (PVCs)
supraventricular tachycardia ventricular co	ouplets
☐ junctional tachycardia ☐ junctional rhy	/thm
ventricular bigeminy ventricular fib	prillation
ectopic atrial rhythm	
ventricular tachycardia (< 30 seconds) > 120 bpm (must fill in a	a & b if this box is checked)
If ventricular tachycardia, please complete:	
a. Length: complexes b. Average Rate:	bpm
If patient is on pacemaker (as indicated above), choose level of paci	ng:
☐ 100% paced ☐ intermittently paced ☐ N/A (If	100% paced, do not complete rest of form)
AV Conduction Abnormalities: (Choose one)	NONE
AV block, 1st degree	
AV block, 2nd degree Mobitz type 1 (Wenkebach)	
AV block, 2nd degree Mobitz type 2	
AV block, 3rd degree	
Abnormalities of P wave: (Choose all that apply)	□NONE
☐ Left atrial enlargement ☐ Right atrial er	nlargement
Abnormalities of QRS axis: (Choose one)	NONE
☐ Left axis deviation(> -30°) ☐ Right axis de	eviation (> +100º)
QRS voltage abnormalities: (Choose all that apply)	NONE
☐ Low voltage ☐ Right ventricu	ular hypertrophy
Left ventricular hypertrophy	



FORM NO. CNA024								
Acrostic Identifier:								
Study ID:								
Date source form comp	leted:/_	/						
				Day of Injec				
Intraventricular conducti	on abnormalities: (	Choo	se al	I that apply)				
Right bundle	branch block, comple	ete		Left bun	idle branch bloc	k, complete		
Right bundle	branch block, incomp	olete		Left bun	idle branch bloc	k, incomplete		
Left anterior f	ascicular block			Nonspe	cific intraventric	ular conductio	n disturbance	
Left posterior	fascicular block							
				For eac	h "Yes" respons	se, check all lo	cations that a	oply:
Are Q waves present?		Υ		N 🗌	Anterior	Lateral	Inferior	
Is ST segment elevation p	resent?	Υ		N 🗌	Anterior	Lateral [	Inferior	
Is ST segment depression	present?	Υ		N 🗌	Anterior	Lateral	Inferior	
Is T wave inversion preser	nt?	Υ		N 🗌	Anterior	Lateral [	Inferior	
Is there evidence of poster	rior infarction?	Υ		N 🗌		Abn. ST depression V <sub>1</sub> , V <sub>2</sub>	Abn. ST elevation $V_1, V_2$	
Is there evidence of RV inf precordial leads)?	arction (right	Υ		N 🗆	N/A □			
Are there nonspecific ST a abnormalities present?	nd/or T wave	Υ		N 🗆				
Comments:								
PI Signature	Initials					Date:		



	T	T		
FORM #	DESCRIPTION of FOCUS FORMS	FOCUS Excel Wkbk tab name		
CNA099	Screening/Demographics	Enrollmt		
CNA001	Eligibility	Elig		
CNA003	Baseline Risk Factors & Other Cardiac Hx	Risk		
CNA004	Baseline Non Cardio. Med. Hx	Med Hx		
CNA005	Physical Exams	BSL PE/PE		
CNA007	Treatment Checklist	Treatment		
CNA011	Medication List	Meds		
CNA012	Medication Allergies	Meds		
CNA021	Labs (Panels)	Labs-panels		
CNA022	Labs (M12)	Labs-M12		
CNA023	Holter	Holter		
CNA024	ECG	ECG		
CNA026	Labs (Interim)	Labs-Interim		
CNA027	Six Minute Walk Test	Walk Test		
CNA029	Bone Marrow Aspiration	Aspir		
CNA031	Study Product Injection	SPI		
CNA041	Adverse Event	AE		
CNA042	Serious Adverse Event	SAE		
CNA043	Unanticipated Problem	UP		
CNA044	Protocol Deviation	Prot Dev		
CNA045	Schedule of Procedures	Sched Proc		
CNA047	Data Glossary			
CNA048	Missing Form	Missing		
CNA051	End of Study	End		
CNA061	Minnesota Living with Heart Failure Questionnaire	MLHF		
CNA062	SF-36	SF-36		
CNA070	Phone Call Follow-up			



FORM NO. CNA045						
Acrostic Identifier:						
Study ID:						
Schedule of Procedures FOCUS						
Procedures	Time Window					
Screening/Baseline	Consent + 50 days					
Screen/Demographics						
Eligibility (Inclusion/Exclusion criteria)						
Baseline Labs						
Baseline Non-Cardiovascular History						
Baseline Risk Factors						
Baseline Allergies Baseline Medications						
Baseline PE						
Baseline Chest xray						
Baseline 6 min walk test						
Quality of Life Questionnaires						
Baseline ECG						
Baseline Holter						
ICD Interrogation (if applicable)						
Baseline TMT with MVO2 (core)						
Time of Test:						
Baseline SPECT (core)						
Baseline Echo w/contrast (core)						
Treatment Checklist  Aspiration/Injection (SPI)	SPI					
Day of Injection PE	SFI					
Biorepository blood draws (if consented)						
Bone Marrow Aspiration						
Baseline cMRI (if applicable) (core)						
Cell Processing						
Cell Processing - Post Release	SPI + 14 days					
Study Product Infusion						
ECG						
Holter						
Routine Echo immediately post procedure						
Routine Echo 4-6 hrs post procedure	CDL + 1 doy					
Day after Injection  Day after Injection PE	SPI + 1 day					
Biorepository blood draws (if consented)						
Labs						
ECG						
1 Week	SPI + 7 days +/- 2 days					
PE						
Labs						
Holter						
Routine Echo						
ECG A Weeks	CDI . 20 device . / F device					
4 Weeks	SPI + 30 days +/- 5 days					
Labs						
Biorepository blood draws (if consented)						
ECG						
Holter						
<u> </u>						



1 0 0 0 0 1 1 0 1 0						
FORM NO. CNA045						
Acrostic Identifier:						
Study ID:						
Schedule of Pro	cedures FOCUS					
Procedures	Time Window					
3 Month	SPI + 90 days +/- 7 days					
PE						
Labs						
Biorepository blood draws (if consented)						
Holter						
ICD Interrogation (if applicable)						
Routine Echo						
ECG						
Quality of Life Questionnaires						
6 Month	SPI + 180 days +/- 30 days					
PE						
Labs						
ECG						
Biorepository blood draws (if consented)						
Holter						
Echo w/contrast (core)						
Chest xray						
6 min walk test						
Quality of Life Questionnaires						
cMRI (if applicable) (core)						
TMT with MVO2 (core)						
SPECT (core)						
ICD Interrogation (if applicable)						
12 Month	SPI + 365 days +/- 30 days					
PE						
ECG						
Labs						
Quality of Life Questionnaires						
24 Month	SPI + 730 days +/- 30 days					
Telephone F/U						
36 Month	SPI + 1095 days +/- 30 days					
Telephone F/U						
48 Month	SPI + 1460 days +/- 30 days					
Telephone F/U						
60 Month	SPI + 1825 days +/- 30 days					
Telephone F/U						
End of Study						



#### Cardiovascular Cell Therapy Research Network

FOCUS Protocol Workbook

		FOCUS Labs by Visit Time I	Point	
Baseline	Day After Injection	Weeks 1 & 4	Months 3 & 6	Month 12
CBC with Differential	CBC with Differential	CBC with Differential	CBC with Differential	
WBC	WBC	WBC	WBC	
RBC	RBC	RBC	RBC	
Hgb	Hgb	Hgb	Hgb	
Hct	Hct	Hct	Hct	
MCV	MCV	MCV	MCV	
Platelets	Platelets	Platelets	Platelets	
WBC Differential	WBC Differential	WBC Differential	WBC Differential	
Neutrophilis	Neutrophilis	Neutrophilis	Neutrophilis	
Lymphocytes	Lymphocytes	Lymphocytes	Lymphocytes	
Monocytes	Monocytes	Monocytes	Monocytes	
Eosinophils	Eosinophils	Eosinophils	Eosinophils	
Basophils	Basophils	Basophils	Basophils	
Cardiac Enzymes	Cardiac Enzymes**	Cardiac Enzymes	Cardiac Enzymes	
Troponin I or T	Troponin I or T	Troponin I or T	Troponin I or T	
CK	CK	CK	CK	
CK-MB	CK-MB	CK-MB	CK-MB	
Chem-8				
Na+				
K+				
Chloride				
CO <sub>2</sub>				
Glucose				
BUN				
Creatinine				
Calcium				
Liver Function Tests	Liver Function Tests	Liver Function Tests	Liver Function Tests	
Bilirubin-Total	Bilirubin-Total	Bilirubin-Total	Bilirubin-Total	
Bilirubin-Direct	Bilirubin-Direct	Bilirubin-Direct	Bilirubin-Direct	
Total Protein	Total Protein	Total Protein	Total Protein	
Alk Phos	Alk Phos	Alk Phos	Alk Phos	
ALT	ALT	ALT	ALT	
AST	AST	AST	AST	
Other Tests	Other Tests	Other Tests	Other Tests	Other Tests
BNP	BNP	BNP	BNP	BNP
hsCRP	hsCRP	hsCRP	hsCRP	
PTT	BUN	BUN	BUN	
PT/INR	Creatinine	Creatinine	Creatinine	
Pregnancy Test*		Pregnancy Test* (wk 4)	Pregnancy Test*	Pregnancy Test*

<sup>\*</sup> Other Tests/Pregnancy: women of childbearing potential

<sup>\*\*</sup> Day After Infusion/Cardiac Enzymes: collected every 8 hours post infusion



FORM NO. CNA09	9		
Date form completed	: <u> </u>		
Scre	eening / Demograp	hics	
Last Name:			
First Name:			
Middle Initial:			
Consent signed	Biorepository consent signed	☐ Yes ☐ No	
Date of Birth			
Sex	$M \square F \square$		
Hispanic	N 🗌 Y 🗌		
Race (choose one)	:		
White			
Black or African	American		
Asian			
Native Hawaiian	or Other Pacific Isl	ander	
American Indian	or Alaska Native		
Other			
Marital Status (choo	ose one):		
Married			
Living with a par	tner		
Single/never ma	rried		
Widowed			
Divorced			
Separated			
Entered to eCRF	Initials		



FORM	NO. CN.	A001						
Acrostic	: Identifi	er:						
Study II								
Date so	urce for	m completed:/						
	Eligibility Criteria							
Y	N	Inclusion Criteria (Must answer Yes to all questions to be eligible)						
		Patient is at least 18 years of age.						
		Patient has significant coronary heart disease not amenable to revascularization.						
		Left ventricular ejection fraction ≤ 45% as assessed by echocardiogram.						
		Limiting angina (Class II to IV) and/or CHF (NYHA Class II - III).						
		Patient is on maximal medical therapy. <u>Maximal medical therapy for anginal symptoms</u> is defined as a medical regimen that includes the maximal tolerated dose of at least two antiangina medications, such as beta-blockers, nitrates, or calcium-channel blockers. One anticipates using a beta blocker or calcium channel blocker to reduce heart rate to 50-60 beats per minute and systolic blood pressure to 100-115 mm Hg in patients with angina or as tolerated clinically in order to evaluate them for limiting angina or angina that interferes with the life style the patient wishes to lead. <u>Maximal medical therapy for heart failure symptoms</u> includes beta-blockers (either a beta 1 blocker, such as metoprolol or non-specific beta blocker, such as carvedilol), ACE-1 or ARB (if creatinine ≤ 2.5) + diuretics.						
		Presence of reversibility as identified by SPECT (isotope protocol) and/or viability as identified by NOGA.						
		Coronary artery disease not well suited to any other type of revascularization procedure (percutaneous or surgical) in the target region of the ventricle. A cardiovascular surgeon and an interventional cardiologist (who are not investigators in the trial) will assess the subject's eligibility by chart review and recent diagnostic arteriogram (within 12 months) to determine percutaneous or surgical revascularization options. Patients should not be considered for revascularization procedures if they have an unsuitable coronary anatomy, including: total occlusion, poor targets for bypass grafts, small vessels, or diffuse disease affecting the distal vessel and making proximal revascularization ineffective. Patients could also have significant co-morbidities that would pose an unacceptable risk for surgical revascularization.						
		Hemodynamic stability as defined by systolic BP ≥ 80 mmHg without IV pressors or support devices.						
		Females of childbearing potential must be willing to use two forms of birth control for the duration of the study. (If male, check "Y")						
		Consent signed on/						
Υ	N	Exclusion Criteria (Must answer No to all questions to be eligible)						
		Atrial fibrillation or flutter without a pacemaker that guarantees a stable heart rate.						
		Unstable angina.						
		LV thrombus, as documented by echocardiography or LV angiography.						
		A vascular anatomy that precludes cardiac catheterization.						
		Severe valvular disease or mechanical aortic valve that would preclude safe entry of the catheter into the left ventricle.						
		Pregnant or lactating status. Pregnancy as determined by a positive urine pregnancy test at baseline.						
		Platelet count < 100 K/mm <sup>3</sup> .						



FORM NO. C	NA001						
Acrostic Iden	tifier:						
Study ID:							
Date source	Date source form completed:/						
	<b>—</b>	Eligibility Criteria					
YN	=	ion Criteria continued (Must answer No to all questions to be eligible)					
	_	2 K/mm <sup>3</sup> .					
	Revasc	ularization within 30 days.					
	TIA or s	stroke within 60 days of study enrollment.					
	☐ ICD sho	ock within 30 days of baseline screening.					
		ce of sustained ventricular tachycardia (30 or more seconds) on 24 hour Holter monitor performed during screening period.					
	A bleed	ing diathesis defined as an INR ≥ 2.0 in the absence of warfarin therapy.					
		ry of malignancy in the last 5 years excluding basal cell carcinoma that has been lly removed with proof of surgical clean margins.					
	☐ Has a k	nown history of HIV, or has active Hepatitis B or active Hepatitis C.					
	Any pre	vious transplant requiring immunosuppressive medication.					
	evaluati electroo	risk acute coronary syndrome (ACS) or a myocardial infarction in the month prior to ion. (ACS is defined as the presence of chest pain characteristic for angina, dynamic cardiography changes of ST segment depression or elevation and/or serum elevation on I or T > 3X ULN (according to local laboratory)).					
		entricular wall thickness of <8 mm (by echocardiogram) of the infero-lateral wall at the ite for cell injection.					
	separat	to walk on a treadmill except for class IV angina patients who will be evaluated ely. (If only reason patient is unable to walk on treadmill is class IV angina, then patient ncluded.)					
	Potentia days.	al patients enrolled in an investigational device or drug study within the previous 30					
		dysfunction, as defined as aspartate aminotransferase (AST) and /or alanine anferase (ALT) > 1.5X ULN prior to study entry.					
	Chronic	renal insufficiency as defined as a serum creatinine > 2.5 mg/dL or requires dialysis.					
		er condition that in the judgment of the investigator would be a contraindication to ent or follow-up.					
YN	Specia	I Criteria (Must answer No to first question OR Yes to both to be eligible)					
	III or an	be patient meet the following criteria: LVEF $\leq$ 35%; sinus rhythm; NYHA functional class obbulatory class IV symptoms despite recommended, optimal medical therapy; and has dyssynchrony (QRS duration > 0.12 ms)?					
	Did the	patient who met the criteria above receive cardiac resynchronization therapy?					



FORM NO. CNA001				
Acrostic Identifier:				
Study ID:				
Date source form comp	oleted: /			
		Eligibility Criteria		
	9	g the screening process; no ssed with the patient have be	t all data were collected to answer een answered	
An inclusion or exclusion criteria exemption, or approval for the most recent protocol amendment, has been granted by the CCTRN Medical Monitor or IRB respectively on one or more of the above items (comment required with a brief explanation; include detail if multiple criteria are involved)				
PI Signature			Date:	
RNC Signature			Date:	
Entered to eCRF	Initials _			



FORM NO. CNA003	
Acrostic Identifier:	
Study ID:	
Date source form completed:/	<u></u>
	Baseline Risk Factors
Diabetes	No  Type I  Type II
<u>Diabetes Treatment:</u>	Oral Hypoglycemics
	Insulin
	Neither U
Hypertension	No  Yes
<u>Hypertension Treatment:</u>	1 medication
	2 or more meds
Llynoulinidomio	No medication
Hyperlipidemia Hyperlipidemia Treatment:	No  Yes  Diet controlled
<u>riypenipidenila rreatinent.</u>	Drug controlled
	Neither
History of MI	No ☐ Yes ☐ Unknown ☐
	If yes, date most recent://
History of CABG	No ☐ Yes ☐ Unknown ☐
•	If yes, date most recent://
	Total number vessels bypassed:
	Total number of CABG operation(s):
History of Congestive Heart Failure	No ☐ Yes ☐ Unknown ☐
History of cancer	No ☐ Yes ☐ Unknown ☐
	If yes, type of cancer:
	Date of diagnosis://
History of renal insufficiency	No ☐ Yes ☐ Unknown ☐
History of allergies	No ☐ Yes ☐ Unknown ☐
	If yes, list:
Family history of premature CAD	No □ Yes □ Unknown □
(males <55 females <65)	
Angina Date most recent://_	No Stable Unstable
Carotid Disease, asymptomatic	No Ses
History of TIAs or CVAs	No  Yes  If yes, date most recent: _/_/_
History of valvular heart disease	No  Yes
If yes, check all that apply:	mitral
	aortic 🗆
	pulmonic
History of Aneurysm	No  Yes
Thatory of Alleuryalli	



FORM NO. CNA003					
Acrostic Identifier:					
Study ID:					
Date source form completed:/_					
	Base	line F	Risk Facto	ors	
History of Stroke	No		current deficit		completely resolved
History of PVD	No		Yes		
History of arrhythmias	No		Yes	-	Unknown   , type:  of onset://
History of bleeding diathesis	No		Yes		Unknown   , please describe in Comments
Obese or history of obesity	No		Yes		
Smoking	Never		Previous Yr stopped		Current  packs/day:
	Othe	r Card	diac Histo	ry	
Please describe interventions in the Conmore than once) and the specific vessel		ion inc	luding num	ber of	interventions (if same procedure done
Prior to this hospitalization, have you	u been hos	pitaliz	ed for:		If yes, Date
Congestive Heart Failure	No		Yes		
Revascularizations	No		Yes		
Previous MI	No		Yes		
Bypass surgery	No		Yes		
Cardiac catheterization	No		Yes		
Cardiac pacemaker	No		Yes		
Other coronary interventions	No		Yes		
If yes, please describe other coron	ary interve	ntions	s:		
Procedure:					Date:
1.					
2.					
3. 4.					
5.					
Questions:					'
	No		Yes		N/A □
If female, is patient of child bearing potential?		ு no, cl		ം ost me	enopausal  surgically sterile



FORM NO. CNA003	
Acrostic Identifier:	
Study ID:	
Date source form completed:/_	<u></u>
	Baseline Risk Factors
Questions:	
Has perfusion scan been performed in the last three months?	No □ Yes □
	If yes, date://  Type of scan: MRI  SPECT PET Stress Echo   Were there reversible defects present? No Yes
Comments:	1 100 -
Entered to eCRF	Initiala
EIIICICU IO CORF LI	Initials



FORM NO. CNA004									
Acrostic Identifier:									
Study ID:									
Date source form completed://									
Baseline Non-Cardiovascular Medical History									
System	Not discussed	Unremarkable	Abnormal	Describe the abnormality					
Ears, Nose, Throat									
Opthalmic									
Respiratory									
GI									
Renal									
Urogenital									
Neurologic									
Endocrine									
Musculoskeletal									
Skin									
Psychiatric									
Other									
Entered to eCRF	Initials								



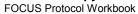
FORM NO. CNA012									
	stic Identifier:								
Study	ı ID:								
Date :	source form cor	mpleted:/_							
			Medi	ication Alle	rgies				
Dru	Drug Allergies NKDA ☐ Yes ☐ Please list:								
FORI	M NO. CNA01	11							
	stic Identifier:								
Study	/ ID:								
Date :	source form cor	mpleted:/_							
			ľ	Medications	3				
	Medicat	tion Class	Medication Name	Dose	Unit	Frequency	Prior to Study Start	Start Date	Stop Date
1									
2									
3									
4									
5									
6									
7									
8									
9									
10									
11									
12									
13									
14									
15									
16									
17									
18									
Comm	ents								

13 of 31

Entered to eCRF

Initials \_\_\_\_\_

#### Cardiovascular Cell Therapy Research Network





#### Medication eCRF drop down list:

**Drug Classes** 

Allopurinol

Angiotensin converting enzyme inhibitors

Antianginal Antiarrhythmics Antibiotics Anticoagulants

Antiplatelet agents (non-aspirin)

Aspirin Beta blockers

Calcium channel blockers Cholesterol-lowering agents

Digitalis Diuretics Inotrope Insulin Nitrates

Non-ACE inhibitor arterial vasodilators (e.g. hydralazine)

Non-insulin hormones Oral hypoglycemics Other antihypertensives Pain medications Potassium Supplements

Sympathetic blockers

Tranquilizers Vaccines Vasodilators Others Units CAP=capsule g=gram GR=grain GTT=drop IU=internationa

IU=international units mg=milligram mL=milliliter oz=ounce PUF=puff SPY=spray/squirt SUP=suppository TAB=tablet TBS=tablespoon TSP=teaspoon U=units ug=microgram

UNK=unknown OTH=other (specify)

uL=microliter

Frequency
BID=twice daily
ONCE=one dose
per hour
per minute
PRN=as needed
QD=once daily
QID=4 times/day
QOD=everyother day

TID=3 times/day

OTH=other (specify)



FORM NO. CNA024	
Acrostic Identifier:	
Study ID:	
Date source form completed://	
ECG - Baseline	
Date of Procedure://	
PR interval: 0 sec QRS interval: 0 sec QT interval: 0	sec HR: bpm
☐ ECG NORMAL ☐ ECG NOT NORMAL	
Note: If you select "ECG NORMAL", you are done with this form.	
Rhythm: (Check all that apply)	
normal sinus rhythm ventricular demand	pacemaker (VVI)
sinus arrhythmia atrial pacemaker	
sinus bradycardia (<60 bpm) dual chamber pace	maker (DDD)
sinus tachycardia (>100 bpm) wandering pacema	ker
atrial fibrillation accelerated idiover	tricular rhythm
☐ atrial flutter ☐ atrial premature co	mplexes
multifocal atrial tachycardia ventricular prematu	re complexes (PVCs)
supraventricular tachycardia ventricular couplets	i
☐ junctional tachycardia ☐ junctional rhythm	
☐ ventricular bigeminy ☐ ventricular fibrillatio	n
ectopic atrial rhythm	
ventricular tachycardia (< 30 seconds) > 120 bpm <i>(must fill in a &amp; b i</i>	if this box is checked)
If ventricular tachycardia, please complete:	,
a. Length: complexes b. Average Rate: bpn	1
If patient is on pacemaker (as indicated above), choose level of pacing:	
	paced, do not complete rest of form)
AV Conduction Abnormalities: (Choose one)	NONE
AV block, 1st degree	
AV block, 2nd degree Mobitz type 1 (Wenkebach)	
AV block, 3rd degree	
Abnormalities of P wave: (Choose all that apply)	□NONE
☐ Left atrial enlargement ☐ Right atrial enlarge	ment
Abnormalities of QRS axis: (Choose one)	NONE
☐ Left axis deviation(> -30°) ☐ Right axis deviation	ı (> +100°)
QRS voltage abnormalities: (Choose all that apply)	NONE
☐ Low voltage ☐ Right ventricular hy	pertrophy
Left ventricular hypertrophy	



FORM NO. CNA024							
Acrostic Identifier:							
Study ID:							
Date source form complete	d:/	/					
		EC	CG - Baselin	е			
Intraventricular conduction a	abnormalities: (	Choose	all that apply	·)			NONE
Right bundle brar	ich block, compl	ete	Left bu	ndle branch bloc	k, complete		
Right bundle brar	ch block, incom	plete	Left bu	ndle branch bloc	k, incomplete		
Left anterior fasci	cular block		☐ Nonspe	ecific intraventric	ular conduction o	disturbance	
Left posterior faso	cicular block						
			For eac	ch "Yes" respons	e, check all loca	tions that ap	ply:
Are Q waves present?		Υ	N	Anterior	Lateral 🗌	Inferior [	
Is ST segment elevation prese	nt?	Υ	N	Anterior	Lateral 🗌	Inferior [	
Is ST segment depression pre	sent?	Υ	N	Anterior	Lateral	Inferior [	
Is T wave inversion present?		Υ	N	Anterior	Lateral	Inferior	
Is there evidence of posterior i	nfarction?	Υ	□ N □		Abn. ST depression V <sub>1</sub> , V <sub>2</sub>	Abn. ST elevation V <sub>1</sub> , V <sub>2</sub> [	
Is there evidence of RV infarct precordial leads)?	ion (right	Υ	□ N □	N/A □			
Are there nonspecific ST and/o abnormalities present?	or T wave	Υ	□ N □				
Comments:							
PI Signature	No.				Date:		



FORM NO. CNA005								
Acrostic Identifier:								
Study ID:								
Date source form com	pleted:		Ohmeinel En	varra Danas	!! a			
D	,			am - <i>Basel</i>	ine	_		
Date of Exam:/_	/	Visit i	s outside tir	ne window		Reason:		
☐ Informed consent was revised since study start date								
Date patient reconsented:// Consent version:								
	Vital	Signs			NYHA	Class:	CC	S Class:
Height:		inches			I			I
Weight:		pounds						II
Temperature:	°F	oral	auricle		II	I		III
Respirations:	breath	ns/minute			I\	/		IV
Heart rate:	be	ats/minute			□ N	/A		N/A
Blood Pressure:	/ SBP	 DBP	mmHg (sup	ine)	LVEF: _ (by E		Date:	
Review of Systems:								
<u>Organs</u>		<u>Normal</u>	Abnormal	Not Examined		<u>D</u>	<u>escribe</u>	
Skin								
HEENT								
Lungs								
CV								
Abdomen								
Lymph Nodes								
Musculoskeletal								
Neurological								
Other:								
Questions:								
Has the patient experiency yes, complete AE form)	ced any adve	erse events s	since consen	t signed? (If	Yes \[ \]	No 🗌		
Was the NIH Stroke Sca	Was the NIH Stroke Scale assessment completed? (If not done, or if Yes No Evidence of deficit Evidence of							
Was a chest x-ray completed? (If not done, or if result abnormal, please Yes No Abnormal Abnormal								



FORM NO. CNA005			
Acrostic Identifier:			
Study ID:			
Date source form com	pleted://		
	Physical Exam - <i>Baseli</i>	ne	
Questions:			
Was the baseline contras Lab? (If no, please enter	st Echo completed and results sent to the Core a reason in Comments)	Yes No	
Was the baseline SPEC Core Lab? (If no, please	Γ Scanning completed and results sent to the explain in Comments)	Yes No	
	mill Test with MVO2 completed and results sent to ase explain in Comments)	Yes No	Time of Test::
If applicable, was an ICD (If no, please explain in 0	interrogation completed? Comments)	Yes No	N/A 🗌
Has the patient complete (If no, please explain in 0	ed Quality of Life Questionnaires? Comments)	Yes No No	
Has there been a change (If yes, please update me	e in nitrate usage since consent signed? edication form)	Yes No No	N/A 🗌
*Please remember to u	pdate medication form with inter-visit changes t	o medications	
Comments:			
Entered to eCRF	Initials		



FORM NO. CNA021			
Acrostic Identifier:			
Study ID:			
Date source form completed:			
	Labora	tory Tests	- Baseline
Date and time specimen	obtained: D	ate:/_	/ Time:::
CBC with Differential	Result	Unit	Normal Range
WBC		K/mm <sup>3</sup>	4.0-11.0 K/mm <sup>3</sup>
RBC		M/mm <sup>3</sup>	4.0-6.0 M/mm <sup>3</sup>
Hgb		gm/dL	12.0-17.5 gm/dL
Hct		%	33-53%
MCV		fL	78-100 fL
Platelets		K/mm <sup>3</sup>	135-450 K/mm <sup>3</sup>
WBC Differential			
Neutrophilis		%	36-74%
Lymphocytes		%	12-45%
Monocytes		%	0-13%
Eosinophils		%	0-8%
Basophils		%	< 3.0%
Cardiac Markers (Either Tr	oponin T or Trop	onin I shoul	d be completed, NOT both)
Troponin T		ng/ml	0.0-10 ng/ml
Troponin I		ng/ml	0.0-100 ng/ml
CK		U/L	25-10,000 U/L
CK-MB		ng/ml	0.0-250 ng/ml
Chem-8			
Na+		mmol/L	132-148 mmol/L
K+		mmol/L	3.3-5.5 mmol/L
Chloride		mmol/L	95-110 mmol/L
CO <sub>2</sub>		mmol/L	22-32 mmol/L
Glucose		mg/dL	65-110 mg/dL
Calcium		mg/dL	8.0-10.6 mg/dL
BUN		mg/dL	5-26 mg/dL
Creatinine		mg/dL	0.4-1.5 mg/dL



FORM NO. CNA021		
Acrostic Identifier:		
Study ID:		
Date source form completed:		
	Laboratory Tests -	Baseline
Liver Function Tests		
Bilirubin-Total	mg/dL	0.0-1.5 mg/dL
Bilirubin-Direct	mg/dL	0.0-0.4 mg/dL
Total Protein	g/dL	6.0-8.5 g/dL
Alk Phos	U/L	30-150 U/L
ALT	U/L	0-50 U/L
AST	U/L	0-42 U/L
Other Tests		
BNP	pg/ml	0-100 pg/ml
hsCRP	mg/L	0.0-40 mg/L
PTT	seconds	21-39 secs
PT/INR	seconds	< 1.2 secs
Pregnancy Test (women of childbearing potential)		Negative (urine)
☐ Not applicable		< 5.0 mU/ml (quantitative blood)
Comments:		
PI Signature		Date:
Entered to eCRF	Initials	



FORM NO. CNA023									
Acrostic Identifier:									
Study ID:									
Date source/workbook completed://									
Holter Data Form - Baseline									
Date procedure started://	Predominant Rhythm: (mutually exclusive)								
Total recording time::	☐ Sinus Rhythm ☐ Junctional Rhythm								
General:	☐ Paced Rhythm ☐ Ectopic Atrial Rhythm								
Total beats/QRS Complexes: beats	Atrial Flutter / Fibrillation								
Paced beats: beats	Heart Rates:								
Pauses/Longest RR Interval (> 2 secs):	Minimum:beats/min. @:								
Longest pause was seconds @:	Average:beats/min.								
Total number of pauses:	Maximum: beats/min. @:								
Ventricular Arrhythmia Summary:	Supraventricular Arrhythmia Summary:								
Single/PVC: beats	Single/PAC: beats								
Couplets:	Couplets:								
Total number of NSVT Runs (≥ 3 beats)	Total number of SVT Runs								
Number of beats in longest NSVT run	Number of beats in longest SVT run								
Total number of sustained ventricular tachycardia runs	Intermittent Atrial Fibrillation / Atrial Flutter:								
(≥ 30 secs)	☐ Yes ☐ No								
	If yes, total no. of episodes								
	If yes, min.secs (duration of longest episode)								
AV Block: (Choose all that apply)									
☐ Transient AV block, 2nd degree-Mobitz type 1 (Wenkebac	h)								
total no. of episodes	tion of longest episode (secs)								
☐ Transient AV block, 2nd degree-Mobitz type 2	N/A								
total no. of episodes dura	ation of longest episode (secs)								
☐ Transient AV block, 3rd degree ☐ N/A									
total no. of episodes dura	ation of longest episode (secs)								
Comments:									
PI Signature:									
Entered to eCRF Initials									



FORM NO. CNA027	
Acrostic Identifier:	
Study ID:	
Date source form completed://	
Six Minute Walk	Test - Baseline
Date of Walk Test:/	
BASELINE	END OF TEST
Start Time : :	End Time :
Heart Rate bpm	Heart Rate bpm
Stopped or paused?	If yes, explain in Comments including reason
Total distance walked feet Enter 0 if	patient unable to attempt; explain in Comments
Comments:	
Test performed by:	
Entered to eCRF Initials	



#### Cardiovascular Cell Therapy Research Network

Acrostic Identifier:						
Study ID:						
Date source form completed://						
Minnesota Living With Heart Failu	ıre Qu	estionnai	ire - <i>L</i>	Baseli	ne	
MINNESOTA LIVING WITH HEART	ſ FAIL	URE <sup>®</sup> QL	JEST	IONN	IAIRI	
The following questions ask how much your he ife during the past month (4 weeks). After each show how much your life was affected. If a quarter that question.	h que	stion, circ	cle th	ie 0, 1	, 2, 3	3, 4 or 5 to
Did your heart failure prevent you from living as you wanted during the past month (4 weeks) by -	No	Very Little				Very Much
1. causing swelling in your ankles or legs?	0	1	2	3	4	5
<ol><li>making you sit or lie down to rest during the day?</li></ol>	0	1	2	3	4	5
3. making your walking about or climbing	U	1	2	3	4	3
stairs difficult?	0	1	2	3	4	5
<ol><li>making your working around the house or yard difficult?</li></ol>	0	1	2	3	4	5
5. making your going places away from home difficult?	0	1	2	3	4	5
6. making your sleeping well at night	U		2	3	4	
difficult? 7. making your relating to or doing things	0	1	2	3	4	5
with your friends or family difficult?	O	1	2	3	4	5
<ol><li>making your working to earn a living difficult?</li></ol>	0	1	2	3	4	5
<ol><li>making your recreational pastimes, sports or hobbies difficult?</li></ol>	0	1	2	2	4	=
10. making your sexual activities difficult?	0	1 1	2 2	3 3	4 4	5 5
11. making you eat less of the foods you					_	
like?	0	1	2	3	4	5
<ul><li>12. making you short of breath?</li><li>13. making you tired, fatigued, or low on</li></ul>	0	1	2	3	4	5
energy?	O	1	2	3	4	5
14. making you stay in a hospital?	O	1	2	3	4	5
15. costing you money for medical care?	O	1	2	3	4	5
<ul><li>16. giving you side effects from treatments?</li><li>17. making you feel you are a burden to your</li></ul>	0	1	2	3	4	5
family or friends?	O	1	2	3	4	5
18. making you feel a loss of self-control	0	1	2	2	1	5
in your life?	0	1	2 2	3 3	4	5
<ul><li>19. making you worry?</li><li>20. making it difficult for you to concentrate</li></ul>	О	1	2	3	4	5
or remember things?	0	1	2	3	4	5
21. making you feel depressed?	O	1	2	3	4	5
©1986 Regents of the University of Minnesota, All rights resultiving WITH HEART FAILURE® is a registered trademan						

				· o. n.boon						
FORM	NO.CNA062									
Acrost	ic Identifier:									
Study	ID:									
Date fo	orm completed: _		_							
	SF-36 - Baseline									
This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities. Thank you for completing this survey!  For each of the following questions, please mark an $\boxtimes$ in the one box that best describes your answer.										
<b>1.</b> ]	In general, wo	ould you say y	our health is	<b>:</b> Fair	Poor					
	Excellent	Very good	Good	Fall	P001					
	_	_	_	_	_					
2		2	3 <b>L</b>	4						
_	now?	one year ago,	now would y	ou rate your	neann m gene	erar				
	Much better now than one year ago	Somewhat better now than one year ago	About the same as one year ago	Somewhat worse now than one year ago	Much worse now than one year ago					
			<b>▼</b>	4	5					



RM NO.CNA062			
rostic Identifier:			
ıdy ID:			
te form completed://			
SF-36 -	Baseline		
3. The following items are about activ	_		
Does <u>your health now limit you</u> in	these activities?	If so, how	much?
	Yes,	Yes,	No, not
	limited	limited	limited
	a lot	a little	at all
	· •		
	•	·	•
<sup>a</sup> Vigorous activities, such as running, lifti	ng		
heavy objects, participating in strenuous			
sports	1	2	3
Madagata activities such as maving a			
<ul> <li>Moderate activities, such as moving a table, pushing a vacuum cleaner,</li> </ul>			
bowling, or playing golf		2	3
c Lifting or carrying groceries	1	2	3
d Climbing several flights of stairs	1	2	3
<sup>e</sup> Climbing <u>one</u> flight of stairs	1	2	3
f Bending, kneeling, or stooping	□.		
Bending, kneering, or stooping			3
g Walking more than a mile		2	
· · · · · · · · · · · · · · · · · · ·			
h Walking several blocks			
<u> </u>		<del></del>	
Walking one block	1		3
3 Bathing or dressing yourself	1		3



CODMANO ON A COO	
FORM NO.CNA062	
Acrostic Identifier:	
Study ID:	
Date form completed://	
4. During the <u>past 4 weeks</u> , have you had a with your work or other regular daily activing physical health?	
	Yes No
<sup>a</sup> Cut down on the <u>amount of time</u> you spent on work or other activities	
ь Accomplished less than you would like	
Were limited in the <u>kind</u> of work or other activities	
d Had <u>difficulty</u> performing the work or other activities (for example, it took extra effort)	
5. During the <u>past 4 weeks</u> , have you had a with your work or other regular daily activities emotional problems (such as feeling depress)	ities <u>as a result of any</u>
	Yes No
a Cut down on the <u>amount of time</u> you spent on work or other activities	
b Accomplished less than you would like	
Did work or other activities <u>less carefully</u> than usual	

### Cardiovascular Cell Therapy Research Network

			FOCUS Protocol W	OTKDOOK		
FOR	M NO.CNA062					
Acro	stic Identifier:					
Stud	y ID:					
Date	form completed: _	<u> </u>				
			SF-36 - Basel	ine		
6.		oblems interf	o what extent ered with you , or groups?			
	Not at all	Slightly	Moderately	Quite a bit	Extremely	
	_					1
		2		4	5	
7.	None	Very mild	Mild	Moderate	4 weeks?  Severe	Very Sever
	1	2	3	4	5	6
8.	work (includi	ing both worl	ow much did k outside the h	ome and hou	sework)?	normal
	Not at all	A little bit	Moderately	Quite a bit	Extremely	
	1	2	3	4	5	



FORM NO.CNA062								
Acrostic Identifier:								
Study ID:								
Date form completed://	20 D !'							
SF-36 - Baseline								
9. These questions are about ho you during the <u>past 4 weeks</u> . answer that comes closest to t of the time during the <u>past 4 veeks</u> .	For eacl	n quest	ion, plea	ase give	e the on	e		
	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time		
a Did you feel full of pep?		2	3	4	5	6		
ь Have you been a very nervous person?	1	2	3	4	5	6		
dumps that nothing could cheer you up?	🗀 1	2	3	4	5	6		
d Have you felt calm and peaceful?		2	3	4	5	6		
Did you have a lot of energy?	ı	2	3	4	5	6		
f Have you felt downhearted and blue?	1	2	3	4	5	6		
g Did you feel worn out?	ı	2	3	4	5	6		
h Have you been a happy person?	ı	2	3	4	5	6		
Did you feel tired?	<u> </u>	2	3	4	5	6		

		SF-36 - <i>Ba</i>	seline				
G. G. Dacomic							
10. During the <u>past 4 weeks</u> , how much of the time has your <u>physical</u> <u>health or emotional problems</u> interfered with your social activities (like visiting friends, relatives, etc.)?							
All of the time	Most of the time	Some of the time	A little of the time	None of the time			
□¹ 11. How TR	□² RUE or FALSI	E is each of the Definitely true	Mostly D	tatements for  Oon't Mostly now false	you?  Definitel false		
a I seem to get	sick a little easie	Definitely true	Mostly D true k	Don't Mostly false	Definitel		
<ul> <li>I seem to get than other pe</li> <li>I am as healt</li> </ul>		Definitely true  r	Mostly D true k	Don't Mostly false	Definitel		
<ul> <li>I seem to get than other pe</li> <li>I am as healt know</li> <li>I expect my h</li> </ul>	sick a little easie oplehy as anybody I	Definitely true  True  r	Mostly D true k	Don't Mostly false	Definitel false		



Acrostic Identifier:  Study ID:  Date form completed:/							
Treatment Checklist  The following variables are autopopulated from the previously completed Screen/Demograph Eligibility, Baseline Physical Exam and Baseline Laboratory Tests Forms:  Variable Value Criteria  Patient Age Must be ≥ 18 years old at consent date  LVEF Must be ≤ 45%  Temperature Must be ≤ 99.4 °F  CHF NYHA must be II - III and/or  Angina CCS must be II - IV  Systolic BP Must be ≥ 80 mmHg  WBC Must be ≥ 2 K/mm3  PT/INR Must be ≤ 2.0 secs or taking Warfarin  Troponin I or T Must be ≥ 300 ng/ml (Troponin I) or ≤ 30 ng/ml (Tropolic Platelets Must be ≥ 1.5x ULN (≤ 75 U/L)  AST Must be ≤ 1.5x ULN (≤ 61 U/L)							
Treatment Checklist  The following variables are autopopulated from the previously completed Screen/Demograph Eligibility, Baseline Physical Exam and Baseline Laboratory Tests Forms:  Variable Value Criteria  Patient Age Must be $\geq 18$ years old at consent date  LVEF Must be $\leq 45\%$ Temperature Must be $\leq 99.4$ °F  CHF NYHA must be II - III and/or  Angina CCS must be II - IV  Systolic BP Must be $\geq 80$ mmHg  WBC Must be $\geq 2$ K/mm3  PT/INR Must be $\leq 2.0$ secs or taking Warfarin  Troponin I or T Must be $\geq 100$ K and $\leq 500$ K  ALT Must be $\leq 1.5$ x ULN ( $\leq 75$ U/L)  AST Must be $\leq 1.5$ x ULN ( $\leq 61$ U/L)							
The following variables are autopopulated from the previously completed Screen/Demograph Eligibility, Baseline Physical Exam and Baseline Laboratory Tests Forms:     Variable Value Criteria   Patient Age Must be $\geq$ 18 years old at consent date   LVEF Must be $\leq$ 45%   Temperature Must be $\leq$ 99.4 °F   CHF NYHA must be II - III and/or   Angina CCS must be II - IV   Systolic BP Must be $\geq$ 80 mmHg   WBC Must be $\geq$ 2 K/mm3   PT/INR Must be $\leq$ 2.0 secs or taking Warfarin   Troponin I or T Must be $\leq$ 300 ng/ml (Troponin I) or $\leq$ 30 ng/ml (Troponin I) or $\leq$ 30 ng/ml (Something Must be $\leq$ 1.5x ULN ( $\leq$ 75 U/L)   AST Must be $\leq$ 1.5x ULN ( $\leq$ 61 U/L)							
Eligibility, Baseline Physical Exam and Baseline Laboratory Tests Forms:     Variable Value Criteria   Patient Age Must be $\geq 18$ years old at consent date   LVEF Must be $\leq 45\%$ Temperature Must be $\leq 99.4$ °F   CHF NYHA must be II - III and/or   Angina CCS must be II - IV   Systolic BP Must be $\geq 80$ mmHg   WBC Must be $\geq 2$ K/mm3   PT/INR Must be $\leq 2.0$ secs or taking Warfarin   Troponin I or T Must be $\leq 300$ ng/ml (Troponin I) or $\leq 30$ ng/ml (Tropolatelets   ALT Must be $\leq 1.5x$ ULN ( $\leq 75$ U/L)   AST Must be $\leq 1.5x$ ULN ( $\leq 61$ U/L)							
Patient Age Must be ≥ 18 years old at consent date  LVEF Must be ≤ 45%  Temperature Must be ≤ 99.4 °F  CHF NYHA must be II - III and/or  Angina CCS must be II - IV  Systolic BP Must be ≥ 80 mmHg  WBC Must be ≥ 2 K/mm3  PT/INR Must be < 2.0 secs or taking Warfarin  Troponin I or T Must be ≥ 300 ng/ml (Troponin I) or ≤ 30 ng/ml (Tropolic I)  Platelets Must be ≥ 1.5x ULN (≤ 75 U/L)  AST Must be ≤ 1.5x ULN (≤ 61 U/L)	nics,						
LVEF  Must be $\leq 45\%$ Temperature  Must be $\leq 99.4$ °F  CHF  NYHA must be II - III and/or  Angina  CCS must be II - IV  Systolic BP  Must be $\geq 80$ mmHg  WBC  Must be $\geq 2$ K/mm3  PT/INR  Must be $\leq 2.0$ secs or taking Warfarin  Troponin I or T  Must be $\leq 300$ ng/ml (Troponin I) or $\leq 30$ ng/ml (Tropolic I) or $\leq 30$ ng/ml (Tropolic I)  AST  Must be $\leq 1.5x$ ULN ( $\leq 61$ U/L)  Must be $\leq 1.5x$ ULN ( $\leq 61$ U/L)							
Temperature $Must be \le 99.4  ^{\circ}F$ CHF $NYHA must be II - III and/or$ Angina $CCS must be II - IV$ Systolic BP $Must be \ge 80  mmHg$ WBC $Must be \ge 2  K/mm3$ PT/INR $Must be < 2.0  secs  or  taking  Warfarin$ Troponin I or T $Must be \le 300  ng/ml  (Troponin I)  or \le 30  ng/ml  $							
CHF NYHA must be II - III and/or  Angina CCS must be II - IV  Systolic BP Must be $\geq 80$ mmHg  WBC Must be $\geq 2$ K/mm3  PT/INR Must be $\leq 2.0$ secs or taking Warfarin  Troponin I or T Must be $\leq 300$ ng/ml (Troponin I) or $\leq 30$ ng/ml (Troponin I) or $\leq 30$ ng/ml (Troponin I) Must be $\leq 1.5$ ULN ( $\leq 75$ U/L)  AST Must be $\leq 1.5$ ULN ( $\leq 61$ U/L)	Must be ≤ 45%						
AnginaCCS must be II - IVSystolic BPMust be ≥ 80 mmHgWBCMust be ≥ 2 K/mm3PT/INRMust be < 2.0 secs or taking Warfarin	Must be ≤ 99.4 °F						
Systolic BPMust be $\geq 80 \text{ mmHg}$ WBCMust be $\geq 2 \text{ K/mm3}$ PT/INRMust be $\leq 2.0 \text{ secs or taking Warfarin}$ Troponin I or TMust be $\leq 300 \text{ ng/ml (Troponin I) or } \leq 30 \text{ ng/ml (Troponin I)}$ PlateletsMust be $\geq 100 \text{ K}$ and $\leq 500 \text{ K}$ ALTMust be $\leq 1.5 \text{x}$ ULN ( $\leq 75 \text{ U/L}$ )ASTMust be $\leq 1.5 \text{x}$ ULN ( $\leq 61 \text{ U/L}$ )							
WBCMust be $\geq 2$ K/mm3PT/INRMust be $\leq 2.0$ secs or taking WarfarinTroponin I or TMust be $\leq 300$ ng/ml (Troponin I) or $\leq 30$ ng/ml (Tropo	CCS must be II - IV						
PT/INRMust be < 2.0 secs or taking WarfarinTroponin I or TMust be $\leq 300$ ng/ml (Troponin I) or $\leq 30$ ng/ml (Tropolin I)PlateletsMust be $\geq 100$ K and $\leq 500$ KALTMust be $\leq 1.5x$ ULN ( $\leq 75$ U/L)ASTMust be $\leq 1.5x$ ULN ( $\leq 61$ U/L)	Must be ≥ 80 mmHg						
Troponin I or TMust be $\leq 300$ ng/ml (Troponin I) or $\leq 30$ ng/ml (Troponin I)PlateletsMust be $\geq 100$ K and $\leq 500$ KALTMust be $\leq 1.5x$ ULN ( $\leq 75$ U/L)ASTMust be $\leq 1.5x$ ULN ( $\leq 61$ U/L)	Must be ≥ 2 K/mm3						
Platelets         Must be ≥ 100 K and ≤ 500 K           ALT         Must be ≤ 1.5x ULN (≤ 75 U/L)           AST         Must be ≤ 1.5x ULN (≤ 61 U/L)							
ALT Must be ≤ 1.5x ULN (≤ 75 U/L)  AST Must be ≤ 1.5x ULN (≤ 61 U/L)	Must be ≤ 300 ng/ml (Troponin I) or ≤ 30 ng/ml (Troponin T)						
AST Must be ≤ 1.5x ULN (≤ 61 U/L)							
Creatinine   Must be ≤ 2.5 mg/dl							
If any of the variables above have changed since the Baseline Physical Exam or Baseline La Tests and a more recent exam or test has been done, please enter the updated value, date, the re-check.	-						
Variable Value Date Time	-						
LVEF/							
Temperature/							
Angina/CHF/							
Systolic BP/							
WBC/							
PT/INR/							
Troponin I or T/							
Platelets/							
ALT/							
AST/							
Creatinine        //							



FORM NO. CNA007					
Acrostic Identifier:					
Study ID:					
Date form completed://					
Treatment Checklist					
A baseline testing exemption has been granted by the CCTRN Medical Monitor on one or more of the above variables (comment required with a brief explanation; include detail if multiple variables are involved). <b>Answers to questions 1 through 3 below cannot be overridden by this.</b>					
Please answer the following questions:					
1. Are there explanations for abnormal reviews of symptoms on the Baseline Physical Exam that justify the patient's continuation in the study? (If yes, please explain in Comments)	Yes	No 🗌	NA 🗆		
2. Since the baseline exam and tests, has there been a change in the patient's condition that would prohibit continuation in the study? (If yes, please explain in Comments)	Yes	No 🗌			
3. Is there any other reason you think this patient should not continue in the study? (If yes, please explain in the Comments)	Yes $\square$	No 🗌			
Comments:					
Entered to eCRF Initials					



FORM NO. CNA005								
Acrostic Identifier:								
Study ID:								
Date source form co	mpleted: _	/	/					
		Phys	ical Exam	- Day After	Injection			
Date of Exam:/_		☐ Visit i	s outside tir	ne window		Reason:		
Informed consent	was revised	since stud	y start date					
Date patient reconsente	ed: <u>/</u>	1	Consen	t version:				
Vital Signs NYHA Class: CCS Class:								
Weight:		pounds			I			
Temperature:	°F	□oral	auricle					
Respirations:	breath	ns/minute				I		
Heart rate:	be	ats/minute			I\	/	□ IV	
Blood Pressure:	/ SBP	— — — DBP	mmHg (sup	ine)	N	/A	□ N/A	
Review of Systems:	SDF	DDF						
Have changes occurred	since previou	ıs visit?	Yes No	☐ If no, ta	able is compl	ete.		
<u>Organs</u>		<u>Normal</u>	Abnormal	Not Examined		<u>De</u>	<u>escribe</u>	
Skin								
HEENT								
Lungs								
CV								
Abdomen								
Lymph Nodes								
Musculoskeletal								
Neurological								
Other:								
Questions								
Has the patient experience (If yes, complete AE form		adverse eve	ents?		Yes 🗌 N	No 🗌		
Have there been any signal visit? (If yes, please explanation)			cal findings s	ince last	Yes 🗆 1	No 🗆		
Have there been any cha	inges to med	· ·			Yes 🔲 N	No 🗌		



FORM NO. CNA005					
Acrostic Identifier:					
Study ID:					
Date source form co	mpleted:/				
	Physical Exam - Day After	Injection			
Questions					
Was the NIH Stroke Scale assessment completed? (If not done, or if result is evidence of deficit, please explain in comments)  Yes No No evidence of deficit Evidence of deficit					
Were two 10 ml venous blood (purple top tubes) for FACS analysis and one 10 ml venous blood (green top heparin tube) for plasma cryosto-rage drawn to ship to the biorepository?  no, please explain in the Comments)  Verify patient consented to Biorepository before you draw  Biorepository bloods.					
Has there been a change (If yes, please update me	e in nitrate usage since last visit? edication form)	Yes 🗆 No 🗆	N/A 🗆		
*Please remember to u	pdate medication form with inter-visit changes	to medications			
Comments:					
Entered to eCRF	Initials				



FORM NO. CNA021								
Acrostic Identifier:								
Study ID:								
Date source form comp	oleted:/	/						
Laboratory Tests - Day After Injection								
Date and time specim	nen obtained: Da	te:/_	/ Time: : :					
<b>CBC</b> with Differential	Result	Unit	Normal Range					
WBC		K/mm <sup>3</sup>	4.0-11.0 K/mm <sup>3</sup>					
RBC		M/mm <sup>3</sup>	4.0-6.0 M/mm <sup>3</sup>					
Hgb		gm/dL	12.0-17.5 gm/dL					
Hct		%	33-53%					
MCV		fL	78-100 fL					
Platelets		K/mm <sup>3</sup>	135-450 K/mm <sup>3</sup>					
WBC Differential								
Neutrophilis		%	36-74%					
Lymphocytes		%	12-45%					
Monocytes		%	0-13%					
Eosinophils		%	0-8%					
Basophils		%	< 3.0%					
Cardiac Markers (Eithe	er Troponin T or Tropo	nin I should	be completed, NOT both)					
<b>8 hour</b> Date:/_	/ Time:	_:						
Troponin T		ng/ml	0.0-10 ng/ml					
Troponin I		ng/ml	0.0-100 ng/ml					
CK		U/L	25-10,000 U/L					
CK-MB		ng/ml	0.0-250 ng/ml					
<b>16 hour</b> Date:/_	/ Time:	:						
Troponin T		ng/ml	0.0-10 ng/ml					
Troponin I		ng/ml	0.0-100 ng/ml					
CK		U/L	25-10,000 U/L					
CK-MB		ng/ml	0.0-250 ng/ml					
<b>24 hour</b> Date:/_	/ Time:	_:						
Troponin T		ng/ml	0.0-10 ng/ml					
Troponin I		ng/ml	0.0-100 ng/ml					
СК		U/L	25-10,000 U/L					
CK-MB		ng/ml	0.0-250 ng/ml					



FORM NO. CNA021					
Acrostic Identifier:					
Study ID:					
Date source form con	npleted:	/	<u></u>		
	La	boratory T	ests - Da	ay After Injection	
Chem-8					
BUN			mg/dL	5-26 mg/dL	
Creatinine			mg/dL	0.4-1.5 mg/dL	
Liver Function Tests	\$				
Bilirubin-Total			mg/dL	0.0-1.5 mg/dL	
Bilirubin-Direct			mg/dL	0.0-0.4 mg/dL	
Total Protein			g/dL	6.0-8.5 g/dL	
Alk Phos			U/L	30-150 U/L	
ALT			U/L	0-50 U/L	
AST			U/L	0-42 U/L	
Other Tests					
BNP			pg/ml	0-100 pg/ml	
hsCRP			mg/L	0.0-40 mg/L	
Comments:		•	•		
					_
PI Signature					Date:
Entered to eCRE		Init	ials		



FORM NO. CNA024		
Acrostic Identifier:		
Study ID:		
Date source form completed://		
ECG - D	Day After Injection	
Date of Procedure:// Time:	:	
PR interval: 0 sec QRS interval: 0 se	ec QT interval: 0 sec HR: bpm	
☐ ECG NORMAL ☐ ECG NOT NORMAL		
Note: If you select "ECG NORMAL", you are done wi	th this form.	
Rhythm: (Check all that apply)		
normal sinus rhythm	ventricular demand pacemaker (VVI)	
sinus arrhythmia	atrial pacemaker	
sinus bradycardia (<60 bpm)	dual chamber pacemaker (DDD)	
sinus tachycardia (>100 bpm)	wandering pacemaker	
atrial fibrillation	accelerated idioventricular rhythm	
atrial flutter	atrial premature complexes	
multifocal atrial tachycardia	ventricular premature complexes (PVCs)	
supraventricular tachycardia	ventricular couplets	
junctional tachycardia	☐ junctional rhythm	
ventricular bigeminy	ventricular fibrillation	
ectopic atrial rhythm		
ventricular tachycardia (< 30 seconds) > 12	20 bpm (must fill in a & b if this box is checked)	
If ventricular tachycardia, please complete:		
a. Length: complexes b. Ave	erage Rate: bpm	
If patient is on pacemaker (as indicated above), c	choose level of pacing:	
☐ 100% paced ☐ intermittently pace	ed N/A (If 100% paced, do not complete rest	of form)
AV Conduction Abnormalities: (Choose one)		NONE
AV block, 1st degree		
AV block, 2nd degree Mobitz type 1 (Wenk	ebach)	
AV block, 2nd degree Mobitz type 2		
AV block, 3rd degree		
Abnormalities of P wave: (Choose all that apply)		NONE
Left atrial enlargement	Right atrial enlargement	
Abnormalities of QRS axis: (Choose one)	-	NONE
Left axis deviation(> -30°)	Right axis deviation (> +100°)	
QRS voltage abnormalities: (Choose all that apply)		NONE
Low voltage	Right ventricular hypertrophy	
Left ventricular hypertrophy		



FORM NO. CNA024								
Acrostic Identifier:	·						-	
Study ID:								
Date source form comple	eted:/	_/						
ECG - Day After Injection								
Intraventricular conduction	on abnormalities:	(Choo	se al	I that apply)	)			NONE
Right bundle t	oranch block, comp	lete		Left bun	ndle branch bloc	k, complete		
Right bundle b	oranch block, incon	nplete		Left bun	ndle branch bloc	k, incomplete		
Left anterior fa	ascicular block			☐ Nonspe	cific intraventric	ular conductio	n disturbance	
Left posterior	Left posterior fascicular block							
				For eac	h "Yes" respons	e, check all lo	cations that apply	<b>/</b> :
Are Q waves present?		Υ		N□	Anterior	Lateral [	Inferior	]
Is ST segment elevation pr	esent?	Υ		N 🗌	Anterior	Lateral [	Inferior	
Is ST segment depression present? Y		Υ		N 🗌	Anterior	Lateral [	Inferior	]
Is T wave inversion present	t?	Υ		N□	Anterior	Lateral [	Inferior	
Is there evidence of posteri	for infarction?	Υ		N□		Abn. ST depression V <sub>1</sub> , V <sub>2</sub>	Abn. ST elevation $V_1, V_2$	]
Is there evidence of RV infaprecordial leads)?	arction (right	Υ		N 🖂	N/A □			
Are there nonspecific ST and abnormalities present?	nd/or T wave	Υ		N 🖂				
Comments:								
PI Signature						Date:		
Entered to eCRF	Initials	_						



FORM NO. CNA070									
Acrostic Identifier:									
Study ID:									
Date source/workbo	ok completed:	/	/						
		low-Up T							
Visit Type:	☐ Year 2 ☐ `	Year 3	_ Yea	r 4	Y	ear 5	Interim		
Date of Call/Contact	::/								
Contact Initiated by	(check one):		Site			Subjec	t		
Questions being ans	swered by:		Patient	t		Family	Member		Other
Section 1 - Vital Sta	atus								
a. What is the patier	nt's vital status?		Living			Decea	sed		
If decea	ased, what is the kr	nown cau	se of de	eath?					
b. Does the patient h	nave an ICD?		Yes		No		Unknown		
	If yes, estim	ate the da	ate last	fired:					
	Estimate the numb	er of ICD	firings	since					
	the last study cor	ntact (in th	ne last y	ear):					
c. Is the patient on a	n assist device?		Yes		No		Unknown		
		If yes,ind	icate de	vice:					
d. Has the patient ha	ad a heart transplar	nt? 🔲	Yes		No		Unknown		
		If yes, ir	ndicate	date:					
Section 2 - Hospita	lizations and Diag	noses							
Since the last time w	ve spoke to you, ha	ve you ha	ad any h	nospit	aliza	tions fo	r the following	ng?	
e. Heart attack (myo	cardial infarction)		Yes		No		Unknown		
	If yes, pr	ovide est	imated	date:					
f. Bypass surgery (C	ABG)		Yes		No		Unknown		
	If yes, pr	ovide est	imated	date:					
g. Other heart proce balloons, etc.)	dures (caths, stent	· 🗆	Yes		No		Unknown		
1) Describe:					Date	<b>)</b> :			
O) Describer					Dati				
2) Describe:					Date	<b>;.</b>			
3) Describe:					Date	<b>)</b> :			



FORM NO. CNA070	)				
Acrostic Identifier:					
Study ID:					
Date source/workbo	ok completed:/	//			
	Follov	v-Up Telepho	ne Contact		
h. Resuscitative sud	lden death	☐ Yes	☐ No	Unknown	
	If yes, prov	ride estimated	date:		
i. Any cancer diagno	ses (including skin)	☐ Yes	□ No	Unknown	
	If yes, prov	ride estimated	date:		
	Indicate type of cancer(s):				
Comments:			·		
Name of person collecting information:					



### **FORM COMPLETION ATTESTATION**

All of the following forms associated with Baseline Screening have been completed and entered as electronic case report forms in the CCTRN web application, or a missing form has been noted.

1.	CNA099	Screening/Demographics	
2.	CNA001	Eligibility	
3.	CNA003	Baseline Risk Factors & Other Cardiac Histor	у
4.	CNA004	Baseline Non Cardiovascular Medical History	/
5.	CNA011	Medication List*	
6.	CNA012	Medication Allergies*	
7.	CNA024	ECG (Baseline)	
8.	CNA005	Baseline Physical Exam	
9.	CNA021	Baseline Laboratory Tests	
10.	. CNA023	Baseline Holter	
11.	. CNA027	Baseline Six Minute Walk Test	
12.	. CNA061	Minnesota Living with Heart Failure Questio	nnaire
13.	. CNA062	SF-36	
14.	. CNA007	Treatment Checklist	
*CNA0	11 and CNA012	2 are on the same page	
Signati	ure		Date
Printe	d Name		



### **FORM COMPLETION ATTESTATION**

All of the following forms associated with Aspiration/Injection have been completed and entered as electronic case report forms in the CCTRN web application, or a missing form has been noted.

1.	CNA006	Day of Injection Physical Exam		
2.	CNA029	Bone Marrow Aspiration		
3.	CNA031	Study Product Injection		
4.	CNA023	Holter		
5.	CNA024	ECG		
Signat	ure		Date	
J				
Printe	d Name			



### **FORM COMPLETION ATTESTATION**

All of the following forms associated with Day after Injection have been completed and entered as electronic case report forms in the CCTRN web application, or a missing form has been noted.

1.	CNA005	Day after Injection Physical Exam	
2.	CNA021	Day after Injection Laboratory Tests	
3.	CNA024	ECG	
Signat	ure		Date
- 10			
<b>.</b>			
Printe	d Name		



### **FORM COMPLETION ATTESTATION**

All of the following forms associated with Week 1 Follow-up Visit have been completed and entered as electronic case report forms in the CCTRN web application, or a missing form has been noted.

1.	CNA005	Week 1 Physical Exam	
2.	CNA022	Week 1 Laboratory Tests	
3.	CNA023	Holter	
4.	CNA024	ECG	
Signat	uro		Date
Signat	ure		Date
Printe	d Name		



### **FORM COMPLETION ATTESTATION**

All of the following forms associated with Week 4 Follow-up Visit have been completed and entered as electronic case report forms in the CCTRN web application, or a missing form has been noted.

1.	CNA005	Week 4 Physical Exam		
2.	CNA022	Week 4 Laboratory Tests		
3.	CNA023	Holter		
4.	CNA024	ECG		
				_
Signat	ure		Date	
Printe	d Name			



### **FORM COMPLETION ATTESTATION**

All of the following forms associated with Month 3 Follow-up Visit have been completed and entered as electronic case report forms in the CCTRN web application, or a missing form has been noted.

1.	CNA005	Month 3 Physical Exam	
2.	CNA022	Month 3 Laboratory Tests	
3.	CNA023	Holter	
4.	CNA024	ECG	
5.	CNA061	Minnesota Living with Heart Failu	re Questionnaire
6.	CNA062	SF-36	
Signati	ure		Date
Printed	d Name		



### **FORM COMPLETION ATTESTATION**

All of the following forms associated with Month 6 Follow-up Visit have been completed and entered as electronic case report forms in the CCTRN web application, or a missing form has been noted.

1.	CNA005	Month 6 Physical Exam	
2.	CNA022	Month 6 Laboratory Tests	
3.	CNA023	Holter	
4.	CNA024	ECG	
5.	CNA027	Six Minute Walk Test	
6.	CNA061	Minnesota Living with Heart Failure Quest	tionnaire
7.	CNA062	SF-36	
Signat	ure		Date
Printe	d Name		



### **FORM COMPLETION ATTESTATION**

All of the following forms associated with Month 12 Follow-up Visit have been completed and entered as electronic case report forms in the CCTRN web application, or a missing form has been noted.

1.	CNA005	Month 12 Physical Exam		
2.	CNA022	Month 12 Laboratory Test	s	
3.	CNA024	ECG		
4.	CNA061	Minnesota Living with Hea	rt Failure Questionnaire	
5.	CNA062	SF-36		
Signat	ure		Date	
Printe	d Name			



### **FORM COMPLETION ATTESTATION**

All of the following forms associated with Month 24 Follow-up Visit have been completed and entered as electronic case report forms in the CCTRN web application, or a missing form has been noted.

1. CNA070	Telephone F/U	
Signature		Date
Printed Name		



### **FORM COMPLETION ATTESTATION**

All of the following forms associated with Month 36 Follow-up Visit have been completed and entered as electronic case report forms in the CCTRN web application, or a missing form has been noted.

1. CNA070	Telephone F/U	
Signature		Date
Printed Name		



### **FORM COMPLETION ATTESTATION**

All of the following forms associated with Month 48 Follow-up Visit have been completed and entered as electronic case report forms in the CCTRN web application, or a missing form has been noted.

1. CNA070	Telephone F/U	
Signature		Date
Printed Name		



### **FORM COMPLETION ATTESTATION**

All of the following forms associated with Month 60 Follow-up Visit have been completed and entered as electronic case report forms in the CCTRN web application, or a missing form has been noted.

1.	CNA070	Telephone F/U		
2.	CNA051	End of Study		
Signat	ure		Date	
			<u></u>	
Printe	d Name			



FORM NO. CNA005							
Acrostic Identifier:							
Study ID:							
Date source form co	mpleted: _	/	_/				
			Physical E	xam - Mont	h 3		
Date of Exam:/	_/	☐ Visit i	s outside tir	ne window		Reason:	
☐ Informed consent was revised since study start date							
Date patient reconsente	Date patient reconsented:// Consent version:						
	Vital	Signs			NYHA (	Class:	CCS Class:
Weight:		pounds					I
Temperature:	°F	oral	auricle		<u> </u>		
Respirations:	breath	ns/minute				l	☐ III
Heart rate:	be	ats/minute			I\	/	□ IV
Blood Pressure:	/ SBP	 DBP	mmHg (sup	ine)	N.	/A	□ N/A
Review of Systems:	051	<u> </u>					
Have changes occurred	since previou	ıs visit?	Yes No	☐ If no, ta	able is compl	ete.	
<u>Organs</u>		<u>Normal</u>	<u>Abnormal</u>	Not Examined		<u>D</u>	<u>escribe</u>
Skin							
HEENT							
Lungs							
CV							
Abdomen							
Lymph Nodes							
Musculoskeletal							
Neurological							
Other:							
Questions							
Has the patient experienced a new adverse event since the last follow-up visit? (If yes, complete AE form)							
Have there been any sign follow-up visit? (If yes, plant)				nce the last	Yes $\square$ N	10 <u> </u>	
Have there been any chavisit? (If yes, update med			e the last fol	low-up	Yes N	4o 🔲	



FORM NO. CNA005						
Acrostic Identifier:						
Study ID:						
Date source form co	mpleted:/					
	Physical Exam - Monti	h 3				
Questions						
	le assessment completed? (If not done, or if cit, please explain in comments)	Yes No	No evidence of deficit   Evidence of deficit			
Was a routine no contras abnormal, please explain	et Echo completed? (If not done, or if result in comments)	Yes No	Normal			
If applicable, was the ICE (If no, please explain in C	D interrogation completed? Comments)	Yes No	N/A 🗌			
Has the patient complete (If no, please explain in C	d the Quality of Life Questionnaires? Comments)	Yes No				
one 10 ml venous blood drawn to ship to the biore no, please explain in the	• •	Yes  No				
Has there been a change yes, please update medic	e in nitrate usage since the last follow-up visit? (If cation form)	Yes No No	N/A 🗌			
*Please remember to update medication form with inter-visit changes to medications						
Comments:						
Entered to eCRF	Initials					



FORM NO. CNA021							
Acrostic Identifier:							
Study ID:							
Date source form cor	npleted:/	/					
	Lal	boratory Test	s - Month 3				
Date and time speci	Date and time specimen obtained: Date:// Time::						
<b>CBC</b> with Differentia	al Res	ult Unit	Normal Range				
WBC		K/mm <sup>3</sup>	4.0-11.0 K/mm <sup>3</sup>				
RBC		M/mm <sup>3</sup>	4.0-6.0 M/mm <sup>3</sup>				
Hgb		gm/dL	12.0-17.5 gm/dL				
Hct		%	33-53%				
MCV		fL	78-100 fL				
Platelets		K/mm <sup>3</sup>	135-450 K/mm <sup>3</sup>				
WBC Differential							
Neutrophilis		%	36-74%				
Lymphocytes		%	12-45%				
Monocytes		%	0-13%				
Eosinophils		%	0-8%				
Basophils		%	< 3.0%				
Cardiac Markers (Eit	her Troponin T or	Troponin I shou	uld be completed, NOT both)				
Troponin T		ng/ml	0.0-10 ng/ml				
Troponin I		ng/ml	0.0-100 ng/ml				
СК		U/L	25-10,000 U/L				
CK-MB		ng/ml	0.0-250 ng/ml				
Chem-8		·					
BUN		mg/dL	5-26 mg/dL				
Creatinine		mg/dL	0.4-1.5 mg/dL				
Liver Function Tests	s						
Bilirubin-Total		mg/dL	0.0-1.5 mg/dL				
Bilirubin-Direct		mg/dL	0.0-0.4 mg/dL				
Total Protein		g/dL	6.0-8.5 g/dL				
Alk Phos		U/L	30-150 U/L				
ALT		U/L	0-50 U/L				
AST		U/L	0-42 U/L				



FORM NO. CNA021			
Acrostic Identifier:			
Study ID:			
Date source form cor	npleted:	//	
	L	aboratory Tests	s - Month 3
Other Tests			
BNP		pg/ml	0-100 pg/ml
hsCRP		mg/L	0.0-40 mg/L
Pregnancy Test (won childbearing potential  Not applicable			Negative (urine) < 5.0 mU/ml (quantitative blood)
Comments:	•	•	,
PI Signature			Date:
Entered to eCRF		Initials	



FORM NO. CNA023					
Acrostic Identifier:					
Study ID:					
Date source form completed://					
Holter Data F	orm - <i>Month</i> 3				
Date procedure started://	Predominant Rhythm: (mutually exclusive)				
Total recording time:::	Sinus Rhythm				
General:	☐ Paced Rhythm ☐ Ectopic Atrial Rhythm				
Total beats/QRS Complexes: beats	Atrial Flutter / Fibrillation				
Paced beats: beats	Heart Rates:				
Pauses/Longest RR Interval (> 2 secs):	Minimum: beats/min. @ :				
Longest pause was seconds @:	Average:beats/min.				
Total number of pauses:	Maximum: beats/min. @:				
Ventricular Arrhythmia Summary:	Supraventricular Arrhythmia Summary:				
Single/PVC: beats	Single/PAC: beats				
Couplets:	Couplets:				
Total number of NSVT Runs (≥ 3 beats)	Total number of SVT Runs				
Number of beats in longest NSVT run	Number of beats in longest SVT run				
Total number of sustained ventricular tachycardia runs	Intermittent Atrial Fibrillation / Atrial Flutter:				
(≥ 30 secs)	☐ Yes ☐ No				
	If yes, total no. of episodes				
	If yes, min.secs (duration of longest episode)				
AV Block: (Choose all that apply)					
Transient AV block, 2nd degree-Mobitz type 1 (Wenkebach	n)				
total no. of episodes durat	tion of longest episode (secs)				
☐ Transient AV block, 2nd degree-Mobitz type 2	N/A				
total no. of episodes dura	tion of longest episode (secs)				
☐ Transient AV block, 3rd degree ☐ N/A					
total no. of episodes dura	tion of longest episode (secs)				
Comments:					
PI Signature:	_Date:				
Entered to eCRF  Initials					



FORM NO. CNA024	
Acrostic Identifier:	
Study ID:	
Date source form completed:/	
ECG - Month 3	
Date of Procedure:/ Time::	
PR interval: 0 sec QRS interval: 0 sec QT interval: 0 sec HR: bpm	
☐ ECG NORMAL ☐ ECG NOT NORMAL	
Note: If you select "ECG NORMAL", you are done with this form.	
Rhythm: (Check all that apply)	
normal sinus rhythm ventricular demand pacemaker (VVI)	
sinus arrhythmia atrial pacemaker	
sinus bradycardia (<60 bpm) dual chamber pacemaker (DDD)	
sinus tachycardia (>100 bpm) wandering pacemaker	
atrial fibrillation accelerated idioventricular rhythm	
atrial flutter atrial premature complexes	
multifocal atrial tachycardia ventricular premature complexes (PVCs)	
supraventricular tachycardia ventricular couplets	
☐ junctional tachycardia ☐ junctional rhythm	
ventricular bigeminy ventricular fibrillation	
ectopic atrial rhythm	
ventricular tachycardia (< 30 seconds) > 120 bpm (must fill in a & b if this box is checked)	
If ventricular tachycardia, please complete:	
a. Length: complexes b. Average Rate: bpm	
If patient is on pacemaker (as indicated above), choose level of pacing:	
☐ 100% paced ☐ intermittently paced ☐ N/A (If 100% paced, do not complete rest of f	orm)
AV Conduction Abnormalities: (Choose one)	NONE
AV block, 1st degree	
AV block, 2nd degree Mobitz type 1 (Wenkebach)	
AV block, 2nd degree Mobitz type 2	
AV block, 3rd degree	
Abnormalities of P wave: (Choose all that apply)	NONE
☐ Left atrial enlargement ☐ Right atrial enlargement	
Abnormalities of QRS axis: (Choose one)	NONE
☐ Left axis deviation(> -30°) ☐ Right axis deviation (> +100°)	
QRS voltage abnormalities: (Choose all that apply)	NONE
☐ Low voltage ☐ Right ventricular hypertrophy	
Left ventricular hypertrophy	



FORM NO. CNA024								
Acrostic Identifier:								
Study ID:								
Date source form comple	eted:/	/						
			ECG	S - Month 3	3			
Intraventricular conduction	on abnormalities: (	Choo	se all	I that apply)	)			NONE
Right bundle b	Right bundle branch block, complete Left bundle branch block, complete							
Right bundle b	oranch block, incom	olete		Left bun	ndle branch bloc	ck, incomplete		
Left anterior fa	ascicular block			Nonspe	cific intraventric	cular conduction	disturbance	
Left posterior	fascicular block							
				For eac	h "Yes" respons	se, check all loc	ations that a	pply:
Are Q waves present?		Υ		N 🗌	Anterior	Lateral _	Inferior	
Is ST segment elevation pro	esent?	Υ		N 🗌	Anterior	Lateral	Inferior	
Is ST segment depression	present?	Υ		N 🗌	Anterior	Lateral _	Inferior	
Is T wave inversion present	?	Υ		N 🗌	Anterior	Lateral [	Inferior	
Is there evidence of posteri	or infarction?	Υ		N 🗆		R Abn. ST depression $V_1, V_2$	Abn. ST elevation $V_1, V_2$	
Is there evidence of RV infa precordial leads)?	arction (right	Υ		N 🗆	N/A □			
Are there nonspecific ST ar abnormalities present?	nd/or T wave	Υ		N 🗆				
Comments:								
PI Signature						Date:		
Entered to eCRF	Initials							



FOCUS Protocol Workbook							
FORM NO.CNA061							
Acrostic Identifier:							
Study ID:							
Date source form completed:/							
Minnesota Living With Heart Failu	ıre Qu	estionna	ire -	Month	3		
MINNESOTA LIVING WITH HEART						<u> </u>	
The following questions ask how much your heart failure (heart condition) affected your life during the past month (4 weeks). After each question, circle the 0, 1, 2, 3, 4 or 5 to show how much your life was affected. If a question does not apply to you, circle the 0 after that question.  Did your heart failure prevent							
you from living as you wanted during		Very				Very	
the past month (4 weeks) by -	No	Little				Much	
causing swelling in your ankles or legs?     making you sit or lie down to root during.	O	1	2	3	4	5	
<ol> <li>making you sit or lie down to rest during the day?</li> <li>making your walking about or climbing</li> </ol>	0	1	2	3	4	5	
stairs difficult?  4. making your working around the house	O	1	2	3	4	5	
or yard difficult?  5. making your going places away from	0	1	2	3	4	5	
home difficult?  6. making your sleeping well at night	O	1	2	3	4	5	
difficult?  7. making your relating to or doing things	O	1	2	3	4	5	
with your friends or family difficult?  8. making your working to earn a living	О	1	2	3	4	5	
difficult?  9. making your recreational pastimes, sports	O	1	2	3	4	5	
or hobbies difficult?	O	1	2	3	4	5	
<ul><li>10. making your sexual activities difficult?</li><li>11. making you eat less of the foods you</li></ul>	0	1	2	3	4	5	
like?	0	1	2	3	4	5	
12. making you short of breath? 13. making you tired, fatigued, or low on	0	1	2	3	4	5	
energy?	0	1	2	3	4	5	
<ul><li>14. making you stay in a hospital?</li><li>15. costing you money for medical care?</li></ul>	0	1 1	2 2	3 3	4 4	5 5	
16. giving you side effects from treatments?  17. making you feel you are a burden to your	0	1	2	3	4	5	
family or friends?  18. making you feel a loss of self-control	O	1	2	3	4	5	
in your life?	O	1	2	3	4	5	
19. making you worry? 20. making it difficult for you to concentrate	0	1	2	3	4	5	
or remember things? 21. making you feel depressed?	0	1 1	2 2	3	4 4	5 5	
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Entered to eCRF Initials \_\_\_\_\_

_							
FOR	M NO.CNA062						
Acros	stic Identifier:						
Study	y ID:						
Date	form completed: _	//	_				
			SF-36 - Monta	h 3			
This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities. <i>Thank you for completing this survey!</i> For each of the following questions, please mark an $\boxtimes$ in the one box that best							
	scribes your ar	~ -	Pieme i				
1.	1. In general, would you say your health is:						
	Excellent	Very good	Good	Fair	Poor		
			<b>V</b>	<b>—</b> 4			
2.	Compared to now?	one year ago,	how would y	ou rate your	health in gen	eral	
	Much better now than one year ago	Somewhat better now than one year ago	About the same as one year ago	Somewhat worse now than one year ago	Much worse now than one year ago		
	1	2	3	4	5		



FORM NO ONA OCO				
FORM NO.CNA062				
Acrostic Identifier:				
Study ID:				
Date form completed://				
3. The following items are about activities		_		
Does your health now limit you in these activities? If so, how much?				
	Yes, limited a lot	Yes, limited a little	No, not limited at all	
<ul> <li>Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports</li> <li>Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf</li> <li>Lifting or carrying groceries</li> </ul>	🔲 1	2	3	
d Climbing several flights of stairs	1			
<sub>e</sub> Climbing <u>one</u> flight of stairs	1		3	
f Bending, kneeling, or stooping				
g Walking more than a mile	1			
h Walking several blocks	1			
Walking one block	1		3	
j Bathing or dressing yourself	🔲 1		3	



#### Cardiovascular Cell Therapy Research Network

			FOCUS Protocol Workbook						
FOR	M NO.CNA062								
Acro	stic Identifier:								
Stud	y ID:								
Date	form completed: _	///							
			SF-36 - Monti	h 3					
6.		oblems interf	o what extent ered with you , or groups?						
	Not at all	Slightly	Moderately	Quite a bit	Extremely				
						1			
		2		4	5				
7.	None	Very mild	Mild	Moderate	4 weeks?  Severe	Very Sever			
8.	work (includ	ing both worl	now much did k outside the h	ome and hou	sework)?	normal			
	Not at all	A little bit	Moderately	Quite a bit	Extremely				
				4	5				



FORM NO.CNA062								
Acrostic Identifier:								
Study ID:								
Date form completed://								
SF-36 - <i>Month 3</i>								
9. These questions are about how you during the <u>past 4 weeks</u> . I answer that comes closest to the of the time during the <u>past 4 weeks</u> .	For each ne way y	n quest	ion, plea	ase give	e the on	e		
	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time		
<ul><li>Did you feel full of pep?</li><li>Have you been a very nervous person?</li></ul>								
dumps that nothing could cheer you up?	<u> </u>	2	3		5	6		
d Have you felt calm and peaceful?	🔲 1	2	3	4	5	6		
e Did you have a lot of energy?	1	2	3	4	5	6		
Have you felt downhearted and blue?	1	2	3	4	5	6		
g Did you feel worn out?	1	2	3	4	5	6		
h Have you been a happy person?	1	2	3	4	5	6		
i Did you feel tired?	1	2	3	4	5	6		



orm completed	:/				
		SF-36 - <i>M</i> c	onth 3		
<u>health o</u>		<u>oblems</u> interf		he time has you ur social activit	
All of the time	Most of the time	Some of the time	A little of the time	None of the time	
			<b>▼</b>		
	sick a little easie		true k	Don't Mostly thow false	Definite false
	thy as anybody I	П.		□ <sub>3</sub> □ <sub>4</sub>	
ь I am as healt know	• • • • • • • • • • • • • • • • • • • •		2	34	5
know	health to get		_	34	



FORM NO. CNA005								
Acrostic Identifier:								
Study ID:								
Date source form co	mpleted: _		_/					
			Physical E	xam - Mont	h 6			
Date of Exam:/	_/	☐ Visit i	s outside tir	ne window		Reason:		
☐ Informed consent	was revised	since stud	y start date					
Date patient reconsented: / / / Consent version:								
Vital Signs					NYHA Class: CCS Class:			
Weight:		pounds						I
Temperature:	Temperature:°F							II
Respirations:	breath	ns/minute						III
Heart rate:	be	ats/minute			IV	1		IV
Blood Pressure:	/ SBP	——— mmHg (supine)			□ N/A		∐ N/A	
Review of Systems:								
Have changes occurred since previous visit?  Yes No If no, table is complete.								
<u>Organs</u>		<u>Normal</u>	Abnormal	Not Examined		<u>D</u>	<u>escribe</u>	
Skin								
HEENT								
Lungs								
CV								
Abdomen								
Lymph Nodes								
Musculoskeletal								
Neurological								
Other:								
Questions								
Has the patient experience visit? (If yes, complete Al		dverse event	since the las	st follow-up	Yes \[ \] N	lo 🗌		
Have there been any sign follow-up visit? (If yes, plant)				ince the last	Yes $\square$ N	lo 🗆		
Have there been any changes to medications since the last follow-up visit? (If yes, update medication form)								



FORM NO. CNA005			
Acrostic Identifier:			
Study ID:			
Date source form co	mpleted:/		
	Physical Exam - Month	n 6	
Questions			
	le assessment completed? (If not done, or if cit, please explain in comments)	Yes No	No evidence of deficit   Evidence of deficit
Was the MRI (if applicab (If no, please explain in C	le) completed and results sent to the Core Lab? Comments)	Yes No	N/A 🔲
Was the chest x-ray comexplain in comments)	pleted? (If not done, or if result abnormal, please	Yes No	Normal  Abnormal
Was the contrast Echo c (If no, please enter a rea	ompleted and results sent to the Core Lab? son in Comments)	Yes No	
no, please explain in Cor	,	Yes No	
Core Lab? (If no, please		Yes No	Time of Test::
If applicable, was the ICI (If no, please explain in C	Ointerrogation completed? Comments)	Yes No	N/A 🗌
Has the patient complete (If no, please explain in C	d the Quality of Life Questionnaires? Comments)	Yes 🗌 No 🗌	
one 10 ml venous blood drawn to ship to the biore no, please explain in the	·	Yes No 🗆	
Has there been a change yes, please update medie	e in nitrate usage since the last follow-up visit? (If cation form)	Yes No	N/A 🗌
*Please remember to u	odate medication form with inter-visit changes t	o medications	_
Comments:			
Entered to aCRE	Initials		



FORM NO. CNA021			
Acrostic Identifier:			
Study ID:			
Date source form cor	npleted:/_	/	
	Lak	oratory Test	s - Month 6
Date and time speci	men obtained:	Date:	// Time:: :
<b>CBC</b> with Differentia	al Resu	ult Unit	Normal Range
WBC		K/mm <sup>3</sup>	4.0-11.0 K/mm <sup>3</sup>
RBC		M/mm <sup>3</sup>	4.0-6.0 M/mm <sup>3</sup>
Hgb		gm/dL	12.0-17.5 gm/dL
Hct		%	33-53%
MCV		fL	78-100 fL
Platelets		K/mm <sup>3</sup>	135-450 K/mm <sup>3</sup>
WBC Differential			
Neutrophilis		%	36-74%
Lymphocytes		%	12-45%
Monocytes		%	0-13%
Eosinophils		%	0-8%
Basophils		%	< 3.0%
Cardiac Markers (Eit	her Troponin T or	Troponin I shou	uld be completed, NOT both)
Troponin T		ng/ml	0.0-10 ng/ml
Troponin I		ng/ml	0.0-100 ng/ml
СК		U/L	25-10,000 U/L
CK-MB		ng/ml	0.0-250 ng/ml
Chem-8			
BUN		mg/dL	5-26 mg/dL
Creatinine		mg/dL	0.4-1.5 mg/dL
Liver Function Tests	s		
Bilirubin-Total		mg/dL	0.0-1.5 mg/dL
Bilirubin-Direct		mg/dL	0.0-0.4 mg/dL
Total Protein		g/dL	6.0-8.5 g/dL
Alk Phos		U/L	30-150 U/L
ALT		U/L	0-50 U/L
AST		U/L	0-42 U/L



FORM NO. CNA021				
Acrostic Identifier:				
Study ID:				
Date source form con	npleted:	/	/	
		Laborate	ory Tests	s - Month 6
Other Tests				
BNP			pg/ml	0-100 pg/ml
hsCRP			mg/L	0.0-40 mg/L
Pregnancy Test (won childbearing potential  Not applicable				Negative (urine) < 5.0 mU/ml (quantitative blood)
Comments:				,
PI Signature				Date:
Entered to eCRF		Initi	ials	



FORM NO. CNA027	
Acrostic Identifier:	
Study ID:	
Date source form completed:/	/
Six Minute	e Walk Test - Month 6
Date of Walk Test:/	
BASELINE	END OF TEST
Start Time:	End Time:
Heart Rate bpm	Heart Rate bpm
Stopped or paused?	No If yes, explain in Comments including reason
Total distance walked feet Ent	ter 0 if patient unable to attempt; explain in Comments
Comments:	
Test performed by:	
Entered to eCRF  Initials	



Entered to eCRF

# Cardiovascular Cell Therapy Research Network FOCUS Protocol Workbook

FORM NO. CNA023					
Acrostic Identifier:					
Study ID:					
Date source/workbook completed://					
Holter Data Fo	orm - Month 6				
Date procedure started://	Predominant Rhythm: (mutually exclusive)				
Total recording time:::	☐ Sinus Rhythm ☐ Junctional Rhythm				
General:	Paced Rhythm Ectopic Atrial Rhythm				
Total beats/QRS Complexes: beats	Atrial Flutter / Fibrillation				
Paced beats: beats	Heart Rates:				
Pauses/Longest RR Interval (> 2 secs):	Minimum: beats/min. @:				
Longest pause was seconds @::	Average:beats/min.				
Total number of pauses:	Maximum:beats/min. @:				
Ventricular Arrhythmia Summary:	Supraventricular Arrhythmia Summary:				
Single/PVC: beats	Single/PAC: beats				
Couplets:	Couplets:				
Total number of NSVT Runs (≥ 3 beats)	Total number of SVT Runs				
Number of beats in longest NSVT run	Number of beats in longest SVT run				
Total number of sustained ventricular tachycardia runs	Intermittent Atrial Fibrillation / Atrial Flutter:				
(≥ 30 secs)	☐ Yes ☐ No				
	If yes, total no. of episodes				
	If yes, min.secs (duration of longest				
	episode)				
AV Block: (Choose all that apply)					
Transient AV block, 2nd degree-Mobitz type 1 (Wenkebach)	□ N/A				
total no. of episodes duratio	n of longest episode (secs)				
☐ Transient AV block, 2nd degree-Mobitz type 2 ☐ N/	/A				
total no. of episodes duration	on of longest episode (secs)				
☐ Transient AV block, 3rd degree ☐ N/A					
total no. of episodes duration	on of longest episode (secs)				
Comments:					
PI Signature:	Date:				

Initials \_\_\_\_\_



FORM NO. CNA024								
Acrostic Identifier:								
Study ID:								
Date source form completed://								
ECG - Month 6								
Date of Procedure:// Time:	:							
PR interval: 0 sec QRS interval: 0 se	ec QT interval: 0 sec HR:bpm							
☐ ECG NORMAL ☐ ECG NOT NORMAL								
Note: If you select "ECG NORMAL", you are done wi	th this form.							
Rhythm: (Check all that apply)								
normal sinus rhythm	ventricular demand pacemaker (VVI)							
sinus arrhythmia	atrial pacemaker							
sinus bradycardia (<60 bpm)	dual chamber pacemaker (DDD)							
sinus tachycardia (>100 bpm)	wandering pacemaker							
atrial fibrillation	accelerated idioventricular rhythm							
atrial flutter	atrial premature complexes							
multifocal atrial tachycardia	ventricular premature complexes (PVCs)							
supraventricular tachycardia	ventricular couplets							
junctional tachycardia	iunctional rhythm							
ventricular bigeminy	ventricular fibrillation							
ectopic atrial rhythm	_							
	20 bpm (must fill in a & b if this box is checked)							
If ventricular tachycardia, please complete:	, ,							
, , , , , , , , , , , , , , , , , , ,	erage Rate: bpm							
If patient is on pacemaker (as indicated above), c	•							
☐ 100% paced ☐ intermittently pace		f form)						
AV Conduction Abnormalities: (Choose one)	(ii 100% pasea, as not semplete lest e	NONE						
AV block, 1st degree	_							
AV block, 2nd degree Mobitz type 1 (Wenk	ebach)							
AV block, 2nd degree Mobitz type 2	,							
AV block, 3rd degree								
Abnormalities of P wave: (Choose all that apply)		NONE						
Left atrial enlargement	Right atrial enlargement							
Abnormalities of QRS axis: (Choose one)		NONE						
Left axis deviation(> -30°)	Right axis deviation (> +100°)							
QRS voltage abnormalities: (Choose all that apply)		NONE						
Low voltage	Right ventricular hypertrophy							
Left ventricular hypertrophy								



FORM NO. CNA024							
Acrostic Identifier:							
Study ID:							
Date source form completed:/	/						
		ECG	3 - Month	6			
Intraventricular conduction abnormalities	: (Choos	se al	I that apply	)			NONE
Right bundle branch block, con	nplete	Left bundle branch block, complete					
Right bundle branch block, inco	omplete		Left bur	ndle branch bloc	k, incomplete		
Left anterior fascicular block			Nonspe	ecific intraventric	ular conduction	disturbance	;
Left posterior fascicular block							
			For eac	ch "Yes" respons	se, check all loca	itions that a	pply:
Are Q waves present?	Υ		N 🔲	Anterior	Lateral	Inferior	
Is ST segment elevation present?	Υ		N□	Anterior	Lateral	Inferior	
Is ST segment depression present?	Υ		N 🔲	Anterior	Lateral	Inferior	
Is T wave inversion present?	Υ		N 🗌	Anterior	Lateral	Inferior	
Is there evidence of posterior infarction?	Y		N□		Abn. ST depression V <sub>1</sub> , V <sub>2</sub>	Abn. ST elevation V <sub>1</sub> , V <sub>2</sub>	
Is there evidence of RV infarction (right precordial leads)?	Y		N 🖂	N/A □			
Are there nonspecific ST and/or T wave abnormalities present?	Y		N 🗀				
Comments:							
PI Signature					Date:		
Entered to eCRF  Initials							



ORM NO.CNA061						
crostic Identifier:						
tudy ID:						
•						
Pate source form completed://	_				_	
Minnesota Living With Heart Fail	ure Qu	<u>estionna</u>	ire - <i>i</i>	Month	6	
MINNESOTA LIVING WITH HEART	ΓFAIL	URE <sup>®</sup> QU	JEST	IONN	IAIRE	
the following questions ask how much your here during the past month (4 weeks). After each how how much your life was affected. If a quefter that question.	ch que	stion, cire	cle th	ie 0, 1	, 2, 3	, 4 or 5 t
ou from living as you wanted during		Very				Very
ne past month (4 weeks) by -	No	Little				Much
. causing swelling in your ankles or legs?	O	1	2	3	4	5
. making you sit or lie down to rest during						
the day?	O	1	2	3	4	5
. making your walking about or climbing	0		•	2	4	_
stairs difficult?	О	1	2	3	4	5
. making your working around the house or yard difficult?	0	1	2	3	4	5
. making your going places away from	U	1	2	3	4	3
home difficult?	O	1	2	3	4	5
. making your sleeping well at night	O	1	2	3	-	3
difficult?	O	1	2	3	4	5
. making your relating to or doing things	Ü	-	_		•	C
with your friends or family difficult?	O	1	2	3	4	5
. making your working to earn a living				_		_
difficult?	O	1	2	3	4	5
. making your recreational pastimes, sports						
or hobbies difficult?	O	1	2	3	4	5
making your sexual activities difficult?	O	1	2	3	4	5
<ol> <li>making you eat less of the foods you</li> </ol>						
like?	O	1	2	3	4	5
2. making you short of breath?	O	1	2	3	4	5
3. making you tired, fatigued, or low on			-	2		_
energy?	0	1	2	3	4	5
4. making you stay in a hospital?	0	1	2	3	4	5
5. costing you money for medical care?	0	1 1	2 2	3 3	4 4	5 5
<ul><li>6. giving you side effects from treatments?</li><li>7. making you feel you are a burden to your</li></ul>	О	1	2	3	4	3
family or friends?	0	1	2	3	4	5
8. making you feel a loss of self-control	U	1	2	3	4	3
in your life?	0	1	2	3	4	5
9. making you worry?	Ö	1	2	3	4	5
making it difficult for you to concentrate	O	•	_	3	•	5
or remember things?	O	1	2	3	4	5
1. making you feel depressed?	O	1	2	3	4	5
21. making you reel depressed?		Oo not copy				

Entered to eCRF Initials \_\_\_\_\_

	M NO CNIAOCO							
	M NO.CNA062							
	stic Identifier:							
Study	, וטו. form completed: _	1 1						
Date	Tomi completed	/		h 6				
			31-30 - MOIII	11 0				
This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities. Thank you for completing this survey!  For each of the following questions, please mark an $\boxtimes$ in the one box that best								
	cribes your ar	~ -	ions, piease i	uai K áll 🖂 III	i the one box i	mai vest		
ucs	eribes your ar							
1.	In general, we	ould you say y	our health is	:				
	Excellent	Very good	Good	Fair	Poor			
	1	2	3	4	5			
2.	Compared to now?	one year ago,	how would y	ou rate your	health in geno	eral		
	Much better now than one year ago	Somewhat better now than one year ago	About the same as one year ago	Somewhat worse now than one year ago	Much worse now than one year ago			
	1	2		4	5			



FORM NO.CNA062			
Acrostic Identifier:			
Study ID:			
Date form completed://			
SF-36 - Mon	th 6		
3. The following items are about activities	you might	do during a	typical day.
Does your health now limit you in these	e activities?	If so, how	much?
Г			
	Yes,	Yes,	No, not
	limited a lot	limited a little	limited at all
l	a 10t	a IIIIC	
	•	•	•
<sup>a</sup> Vigorous activities, such as running, lifting			
heavy objects, participating in strenuous			
sports			
•			
ь Moderate activities, such as moving a			
table, pushing a vacuum cleaner,			
bowling, or playing golf	1	2	3
c Lifting or carrying groceries			
c Litting of carrying groceries	1	2	3
d Climbing several flights of stairs	Π,		
a Chinoling <u>severar</u> frights of stairs	1		3
<sub>e</sub> Climbing one flight of stairs		2	3
<u> </u>			
f Bending, kneeling, or stooping			3
g Walking more than a mile	1		3
h Walking several blocks		2	3
Walking one block	1		3
j Bathing or dressing yourself	1		3



FORM NO.CNA062
Acrostic Identifier:
Study ID:
Date form completed:/ SF-36 - Month 6
4. During the <u>past 4 weeks</u> , have you had any of the following problem with your work or other regular daily activities <u>as a result of your physical health?</u>
Yes No
a Cut down on the <u>amount of time</u> you spent on work or other activities
ь Accomplished less than you would like
Were limited in the <u>kind</u> of work or other activities
Had <u>difficulty</u> performing the work or other activities (for example, it took extra effort)
5. During the <u>past 4 weeks</u> , have you had any of the following problem with your work or other regular daily activities <u>as a result of any emotional problems</u> (such as feeling depressed or anxious)?
Yes No
a Cut down on the <u>amount of time</u> you spent on work or other activities
b Accomplished less than you would like
c Did work or other activities <u>less carefully</u> than usual

#### Cardiovascular Cell Therapy Research Network

			FOCUS Protocol W	OTKDOOK		
FOR	M NO.CNA062					
Acro	stic Identifier:					
Stud	y ID:					
Date	form completed: _	///				
			SF-36 - Monti	h 6		
6.		oblems interf	o what extent ered with you , or groups?			
	Not at all	Slightly	Moderately	Quite a bit	Extremely	
	1	2	3	4	5	
7.	None	Very mild	we you had du	Moderate	4 weeks?  Severe	Very Seven
		2	3	4	5	6
8.			ow much did k outside the h			normal
	Not at all	A little bit	Moderately	Quite a bit	Extremely	
				<b>T</b>		
	1	2	3	4	5	



FORM NO.CNA062						
Acrostic Identifier:						
Study ID:						
Date form completed://						
SF-3	6 - Month	6				
9. These questions are about how you during the <u>past 4 weeks</u> . I answer that comes closest to the of the time during the <u>past 4 weeks</u> .	For each	n quest	ion, plea	ase give	e the on	e
	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
<ul><li>Did you feel full of pep?</li><li>Have you been a very nervous person?</li></ul>						
dumps that nothing could cheer you up?		2	3		5	6
d Have you felt calm and peaceful?	🔲 1	2	3	4	5	6
Did you have a lot of energy?	1	2	3	4	5	6
Have you felt downhearted and blue?	1	2	3	4	5	6
g Did you feel worn out?	1	2	3	4	5	6
h Have you been a happy person?	1	2	3	4	5	6
i Did you feel tired?	1	2	3	4	5	6



		SF-36 - <i>Mo</i>	onth 6				
10. During the <u>past 4 weeks</u> , how much of the time has your <u>physica health or emotional problems</u> interfered with your social activities (like visiting friends, relatives, etc.)?							
All of the time	Most of the time	Some of the time	A little of the				
Time	Time	Time	Time	time			
			4	5	5		
1. How TR	RUE or FALSI	E is <u>each</u> of the Definitely true		Don't M	s for your dostly false	ou?  Definite false	
I seem to get	sick a little easie	Definitely true	Mostly true	Don't M know	Mostly false	Definite false	
I seem to get than other pe		Definitely true	Mostly true	Don't M	Mostly false	Definite false	
I seem to get than other pe I am as healtl	sick a little easie	Definitely true	Mostly true	Don't M know	Mostly false	Definite false	
I seem to get than other per I am as health know	sick a little easie ople hy as anybody I	Definitely true  True  True  True  True  True	Mostly true	Don't M know	Mostly false	Definite false	



FORM NO. CNA005									
Acrostic Identifier:									
Study ID:									
Date source form completed:/									
Physical Exam - Month 12									
Date of Exam://									
☐ Informed consent was revised since study start date									
Date patient reconsented:// Consent version:									
	Vital	Signs			NYHA	Class:	CCS Class:		
Weight:		pounds							
Temperature:	°F	□oral	auricle		I	l			
Respirations:	breath	ns/minute				II			
Heart rate:	be	ats/minute			□ I\	V	□ IV		
Blood Pressure:	/ SBP	 DBP	mmHg (sup	ine)	□ N/A		□ N/A		
Review of Systems:	SDP	DDP							
Have changes occurred	since previou	ıs visit?	Yes No	☐ If no, ta	able is compl	lete.			
<u>Organs</u>		Normal	Abnormal	Not Examined		D	<u>escribe</u>		
Skin									
HEENT									
Lungs									
CV									
Abdomen									
Lymph Nodes									
Musculoskeletal									
Neurological									
Other:									
Questions									
Has the patient experience visit? (If yes, complete A		lverse event	since the las	st follow-up	Yes 🗌 i	No 🗆			
Have there been any sign follow-up visit? (If yes, pl				nce the last	Yes 🗆 I	No 🗆			
	ollow-up visit? (If yes, please explain in comments)  Have there been any changes to medications since the last follow-up visit? (If yes, update medication form)  Yes No								



FORM NO. CNA005			
Acrostic Identifier:			
Study ID:			
Date source form co	mpleted:/		
	Physical Exam - Month	12	
Questions			
	e assessment completed? (If not done, or if cit, please explain in comments)	Yes No	No evidence of deficit   Evidence of deficit
Has the patient complete (If no, please explain in C	d the Quality of Life Questionnaires?	Yes No No	
Has there been a change yes, please update medic	in nitrate usage since the last follow-up visit? (If cation form)	Yes 🗌 No 🗌	N/A 🔲
*Please remember to up	odate medication form with inter-visit changes	to medications	
Comments:			
PI Signature			Date:
Entered to eCRF	Initials		



FORM NO. CNA024	
Acrostic Identifier:	
Study ID:	
Date source form completed:/	
	ECG - Month 12
Date of Procedure://	Time::
PR interval: 0 sec QRS interval:	0 sec
☐ ECG NORMAL ☐ ECG NOT N	ORMAL
Note: If you select "ECG NORMAL", you a	re done with this form.
Rhythm: (Check all that apply)	
normal sinus rhythm	ventricular demand pacemaker (VVI)
sinus arrhythmia	atrial pacemaker
sinus bradycardia (<60 bpm)	dual chamber pacemaker (DDD)
sinus tachycardia (>100 bpm)	mandering pacemaker
atrial fibrillation	accelerated idioventricular rhythm
atrial flutter	atrial premature complexes
multifocal atrial tachycardia	ventricular premature complexes (PVCs)
supraventricular tachycardia	ventricular couplets
junctional tachycardia	iunctional rhythm
ventricular bigeminy	ventricular fibrillation
ectopic atrial rhythm	_
	conds) > 120 bpm (must fill in a & b if this box is checked)
If ventricular tachycardia, please	
a. Length: complexes	·
If patient is on pacemaker (as indicate	·
	ttently paced N/A (If 100% paced, do not complete rest of form)
AV Conduction Abnormalities: (Choose of	
AV block, 1st degree	<del>-</del>
AV block, 2nd degree Mobitz ty	pe 1 (Wenkebach)
AV block, 2nd degree Mobitz ty	
AV block, 3rd degree	
Abnormalities of P wave: (Choose all that	apply) NONE
Left atrial enlargement	Right atrial enlargement
Abnormalities of QRS axis: (Choose on	
Left axis deviation(> -30°)	☐ Right axis deviation (> +100°)
QRS voltage abnormalities: (Choose all th	nat apply) NONE
Low voltage	Right ventricular hypertrophy
Left ventricular hypertrophy	



FORM NO. CNA024								
Acrostic Identifier:								
Study ID:								
Date source form comple	eted:/	/						
		E	ECG	- Month 1	2			
Intraventricular conduction	on abnormalities: (0	Choos	se al	l that apply)				
Right bundle b	oranch block, comple	ete		Left bun	dle branch blo	ck, complete		
Right bundle b	oranch block, incomp	lete		Left bun	dle branch blo	ck, incomplete		
Left anterior fa	ascicular block			Nonspe	cific intraventric	cular conduction	disturbance	
Left posterior	fascicular block							
				For eac	h "Yes" respon	se, check all loc	ations that ap	oply:
Are Q waves present?		Υ		N 🗌	Anterior	Lateral	Inferior	
Is ST segment elevation pr	esent?	Υ		N 🗌	Anterior	Lateral _	Inferior	
Is ST segment depression	present?	Υ		N 🗌	Anterior	Lateral	Inferior	
Is T wave inversion present	t?	Υ		N 🗌	Anterior	Lateral _	Inferior	
Is there evidence of posteri	or infarction?	Y		N 🗆		R Abn. ST depression $V_1, V_2$	Abn. ST elevation $V_1, V_2$	
Is there evidence of RV infaprecordial leads)?	arction (right	Υ		N 🗆	N/A □			
Are there nonspecific ST an abnormalities present?	nd/or T wave	Υ		N 🗆				
Comments:								
PI Signature						Date:		
Entered to eCRF	Initials							



FORM NO. CNA022							
Acrostic Identifier:							
Study ID:							
Date source form con	npleted:	/	_/				
		Laborato	ory Tests	- Month 12			
Date and time specimen obtained: Date:// Time: :							
Test		Result	Unit	Normal Range			
BNP			pg/ml	0-100 pg/ml			
Pregnancy Test (wor childbearing potential  Not applicable				Negative (urine) < 5.0 mU/ml (quantitative blood)			
Comments:		•	-				
PI Signature				Date:			
Entered to eCRF		Init	ials				



Entered to eCRF

FOCUS Protocol			twoi	N.		
FORM NO.CNA061						
Acrostic Identifier:						
Study ID:						
Date source form completed:/						
Minnesota Living With Heart Failu	iro Ouc	etionnai	ro - /	lonth	12	
						_
MINNESOTA LIVING WITH HEART	HAIL	URE QU	JEST	IONN	IAIRE	=
The following questions ask how much your he life during the past month (4 weeks). After each show how much your life was affected. If a qualiter that question.  Did your heart failure prevent	h ques	stion, circ	cle th	ne 0, 1	, 2, 3	3, 4 or 5 to
you from living as you wanted during		Very				Very
the past month (4 weeks) by -	No	Little				Much
1. causing swelling in your ankles or legs?	O	1	2	3	4	5
<ol><li>making you sit or lie down to rest during the day?</li></ol>	0	1	2	2	4	5
3. making your walking about or climbing	U	1	2	3	4	3
stairs difficult?	O	1	2	3	4	5
<ol><li>making your working around the house</li></ol>						
or yard difficult?	O	1	2	3	4	5
5. making your going places away from	0	1	2	2	4	E
home difficult?  6. making your sleeping well at night	0	1	2	3	4	5
difficult?	O	1	2	3	4	5
7. making your relating to or doing things						
with your friends or family difficult?	O	1	2	3	4	5
8. making your working to earn a living difficult?	0	1	2	3	4	E
9. making your recreational pastimes, sports	0	1	2	3	4	5
or hobbies difficult?	O	1	2	3	4	5
10. making your sexual activities difficult?	O	1	2	3	4	5
11. making you eat less of the foods you						
like?	0	1	2	3	4	5
<ol> <li>making you short of breath?</li> <li>making you tired, fatigued, or low on</li> </ol>	О	1	2	3	4	5
energy?	O	1	2	3	4	5
14. making you stay in a hospital?	Ö	1	2	3	4	5
15. costing you money for medical care?	O	1	2	3	4	5
16. giving you side effects from treatments?	O	1	2	3	4	5
17. making you feel you are a burden to your	0		•	2		_
family or friends? 18. making you feel a loss of self-control	О	1	2	3	4	5
in your life?	O	1	2	3	4	5
19. making you worry?	Ō	1	2	3	4	5
20. making it difficult for you to concentrate						
or remember things?	0	1	2	3	4	5
21. making you feel depressed?	O	1	2	3	4	5
©1986 Regents of the University of Minnesota, All rights resolved WITH HEART FAILURE® is a registered trademan Comments:						

Page 6 of 12 07/19/2010 Workbooks Version 5 - Month 12

Initials \_\_\_\_\_

FORI	M NO.CNA062								
Acros	tic Identifier:								
Study	'ID:								
Date <sup>•</sup>	form completed: _	///	=						
			SF-36 - Month	12					
This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities. <i>Thank you for completing this survey!</i> For each of the following questions, please mark an $\boxtimes$ in the one box that best describes your answer.									
	In general, we		our health is	:					
	Excellent	Very good	Good	Fair	Poor				
			<b>↓</b>						
		ш-							
2.	Compared to now?	one year ago,	how would y	ou rate your	health in geno	eral			
	Much better now than one year ago	Somewhat better now than one year ago	About the same as one year ago	Somewhat worse now than one year ago	Much worse now than one year ago				
			3	4	5				



FORM NO CNASCS				
FORM NO.CNA062				
Acrostic Identifier: Study ID:				
Date form completed://				
SF-36 - <i>Mont</i>	h 12			
3. The following items are about activities  Does your health now limit you in these	-	_		
	Yes, limited a lot	Yes, limited a little	No, not limited at all	
<ul> <li>Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports</li> <li>Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf</li> </ul>				
c Lifting or carrying groceries				
d Climbing several flights of stairs	1	2	3	
<sup>e</sup> Climbing <u>one</u> flight of stairs				
f Bending, kneeling, or stooping	1		3	
g Walking more than a mile	1		3	
h Walking several blocks	1		3	
i Walking one block	1	2	3	
j Bathing or dressing yourself	1	2	3	



FORM NO.CNA062
Acrostic Identifier:
Study ID:
Date form completed://
SF-36 - Month 12
4. During the <u>past 4 weeks</u> , have you had any of the following problems with your work or other regular daily activities <u>as a result of your physical health?</u>
Yes No
a Cut down on the <u>amount of time</u> you spent on work or other activities
ь Accomplished less than you would like 1
Were limited in the <u>kind</u> of work or other activities
Had difficulty performing the work or other activities (for example, it took extra effort)
5. During the <u>past 4 weeks</u> , have you had any of the following problems with your work or other regular daily activities <u>as a result of any emotional problems</u> (such as feeling depressed or anxious)?
Yes No
a Cut down on the <u>amount of time</u> you spent on work or other activities
ь <u>Accomplished less</u> than you would like
c Did work or other activities <u>less carefully</u> than usual

M NO.CNA062 tic Identifier:					
tic Identifier:					
ID:					
form completed: _	///				
		SF-36 - Month	12		
emotional pro	oblems interf	ered with you			
Not at all	Slightly	Moderately	Quite a bit	Extremely	
					'
	2	3	4	5	
None	Very mild  Under the second se	Mild  Mild	Moderate  ———————————————————————————————————	4 weeks?  Severe	Very Sever
					normal
	None  None  None  None  None  V  During the particle of the pa	During the past 4 weeks, to emotional problems interference family, friends, neighbors,  Not at all Slightly	During the past 4 weeks, to what extent emotional problems interfered with your family, friends, neighbors, or groups?    Not at all   Slightly   Moderately	During the past 4 weeks, to what extent has your physemotional problems interfered with your normal soci family, friends, neighbors, or groups?    Not at all   Slightly   Moderately   Quite a bit	SF-36 - Month 12  During the past 4 weeks, to what extent has your physical health emotional problems interfered with your normal social activities of family, friends, neighbors, or groups?  Not at all Slightly Moderately Quite a bit Extremely    Not at all   Slightly   Moderately   Quite a bit   Extremely



FORM NO.CNA062						
Acrostic Identifier:						
Study ID:  Date form completed://						
•	6 - Month	12				
9. These questions are about how you during the past 4 weeks. I answer that comes closest to the of the time during the past 4 weeks.	w you fe For each he way y	el and quest	ion, plea	ase give	e the on	e
	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
<ul><li>Did you feel full of pep?</li><li>Have you been a very nervous person?</li></ul>						
dumps that nothing could cheer you up?	□1	2	3		5	6
d Have you felt calm and peaceful?	1	2	3	4	5	6
e Did you have a lot of energy?	1	2	3	4	5	6
f Have you felt downhearted and blue?	🔲 1	<u></u>	3	4	5	6
g Did you feel worn out?	1		3	4	5	6
h Have you been a happy person?	1	2	3	4	5	6
Did you feel tired?	1	2	3	4	5	6

		SF-36 - Mo	nth 12						
10. During the <u>past 4 weeks</u> , how much of the time has your <u>physica</u> <u>health or emotional problems</u> interfered with your social activities (like visiting friends, relatives, etc.)?									
All of the time	Most of the time	Some of the time	A little of the time	e None of the time					
					'				
1	2	3	4	5					
.1. How TR	RUE or FALSI	E is <u>each</u> of th  Definitely true		statements for Don't Most know false	ly Definite				
a I seem to get	sick a little easie	Definitely true	Mostly true	Don't Most	ly Definite false				
I seem to get than other pe		Definitely true	Mostly true	Don't Most false	ly Definite false				
I seem to get than other pe I am as health know	sick a little easie ople hy as anybody I	Definitely true  True  True  True  True  True	Mostly true	Don't Most know false	ly Definite false				



FORM NO. CNA005	5										
Acrostic Identifier:											
Study ID:											
Date source form co	mpleted: _	/	/								
Physical Exam - Interim											
Date of Exam://											
☐ Informed consent was revised since study start date											
Date patient reconsented:// Consent version:											
Vital Signs NYHA Class: CCS Class:											
Weight:		pounds			I						
Temperature:	°F	□oral	auricle								
Respirations:	breath	ns/minute									
Heart rate:	be	ats/minute			□ IV		□ IV				
Blood Pressure:	/	mmHg (supine)		□ N/A		□ N/A					
Blood Frocouro.	SBP	DBP			LVEF: % (by Echo)		Date:/				
Review of Systems:											
Have changes occurred	since previou	ıs visit?	Yes No	If no, ta	able is comple	ete.					
<u>Organs</u>		<u>Normal</u>	<u>Abnormal</u>	Not Examined		<u>D</u>	<u>escribe</u>				
Skin											
HEENT											
Lungs											
CV											
Abdomen											
Lymph Nodes											
Musculoskeletal						_					
Neurological						_					
Other:											



FORM NO. CNA00	5		
Acrostic Identifier:			
Study ID:			
Date source form co	ompleted:/		
	Physical Exam - Interi	m	
Questions			
Has the patient experien visit? (If yes, complete A	ced a new adverse event since the last follow-up E form)	Yes No No	
, ,	nificant changes in physical findings since the last lease explain in comments)	Yes $\square$ No $\square$	
Have there been any chavisit? (If yes, update med	anges to medications since the last follow-up dication form)	Yes No	
	ale assessment completed? (If not done, or if cit, please explain in comments)	Yes No	No evidence of deficit   Evidence of deficit
Has there been a change yes, please update medi	e in nitrate usage since the last follow-up visit? (If cation form)	Yes 🗌 No 🔲	N/A 🗆
*Please remember to u	pdate medication form with inter-visit changes t	o medications	
Comments:			
Entered to eCRF	Initials		



FORM NO. CNA026			
Acrostic Identifier:			
Study ID:			
Date source form comp	oleted://		
		atory Tests	- Interim
Date and time speci	men obtained: D	ate:/_	/ Time::
CBC with Differentia	al Result	Unit	Normal Range
WBC		K/mm <sup>3</sup>	4.0-11.0 K/mm <sup>3</sup>
RBC		M/mm <sup>3</sup>	4.0-6.0 M/mm <sup>3</sup>
Hgb		gm/dL	12.0-17.5 gm/dL
Hct		%	33-53%
MCV		fL	78-100 fL
Platelets		K/mm <sup>3</sup>	135-450 K/mm <sup>3</sup>
WBC Differential			
Neutrophilis		%	36-74%
Lymphocytes		%	12-45%
Monocytes		%	0-13%
Eosinophils		%	0-8%
Basophils		%	< 3.0%
Cardiac Markers (Eit	her Troponin T or Trop	onin I should	d be completed, NOT both)
Troponin T		ng/ml	0.0-10 ng/ml
Troponin I		ng/ml	0.0-100 ng/ml
СК		U/L	25-10,000 U/L
CK-MB		ng/ml	0.0-250 ng/ml
Chem-8			
Na+		mmol/L	132-148 mmol/L
K+		mmol/L	3.3-5.5 mmol/L
Chloride		mmol/L	95-110 mmol/L
CO <sub>2</sub>		mmol/L	22-32 mmol/L
Glucose		mg/dL	65-110 mg/dL
BUN		mg/dL	5-26 mg/dL
Creatinine		mg/dL	0.4-1.5 mg/dL
Calcium		mg/dL	8.0-10.6 mg/dL



FORM NO. CNA026			
Acrostic Identifier:			
Study ID:			
Date source form comple	eted://		
	Labora	tory Tests -	- Interim
<b>Liver Function Tests</b>			
Bilirubin-Total		mg/dL	0.0-1.5 mg/dL
Bilirubin-Direct		mg/dL	0.0-0.4 mg/dL
Total Protein		g/dL	6.0-8.5 g/dL
Alk Phos		U/L	30-150 U/L
ALT		U/L	0-50 U/L
AST		U/L	0-42 U/L
Other Tests			
BNP		pg/ml	0-100 pg/ml
hsCRP		mg/L	0.0-40 mg/L
PTT		seconds	21-39 secs
PT/INR		seconds	< 1.2 secs
Pregnancy Test (women childbearing potential)			Negative (urine)
☐ Not applicable			< 5.0 mU/ml (quantitative blood)
Comments:			
PI Signature			Date:
Entered to eCRF	Initi	als	



FORM NO. CNA041												
Acrostic Identifier:												
Study ID:												
			Adverse Eve	ent Log								
Date of this Report: _	//		,	_	T							
Outcome Status	Serious	Expectedness	Severity	Relationship to Study / Study Product:	Outcome Attributed to AE				Study Status			
1=Resolved (must have an end date) 2=Ongoing 3=Resulted in SAE (must complete SAE form)	1=Not Serious 2=Serious (must complete SAE form)	1=Expected (refer to IB) 2=Unexpected	1=Mild 2=Moderate 3=Severe 4=Life threatening or permanently disabling 5=Fatal	1=Definite 2=Probable 3=Possible 4=Unlikely 5=Unrelated	1=Resolved, no treatment, no sequelae 2=Resolved, no treatment, with sequelae 3=Resolved with treatment, no sequelae 4=Resolved with treatment and sequelae 5=Still present, no treatment 6=Still present, being treated				Study	1=Continuing in Study 2=Withdrawn		
Description of Event (Diagnosis)		Organ System Classification: 1=HEENT, 2=cardiovascular, 3=abdomen, 4=lungs, 5=renal, 6=neurological, 7=musculoskeletal, 8=skin, 9=lymph nodes, 10=hematological, 11= Other	Start Date (//)	End Date (//)	Outcome Status	Serious	Expectedness	Severity	Relationship to Study/Study Product	Outcome Attributed to AE	Study Status	Narrative added* (progress note)
1.												
2.												
3.												
4.												
5.												
* Narrative should incl	ude the following: det	ailed description of event, prob	lem, and/or product	use error, and releva	ant tests/l	aborator	y data, ir	ncluding	dates	_		
PI Signature		Date:										
RNC Signature		Date:_										
Entered to eCRF	Initials											



FORM NO. CNA	042										
Acrostic Identifier	:										
Study ID:											
			Serious Adverse	Event Log							
Date of this Report:	:/		_								
Outcome Status	Expectedness	Severity	Relationship to Study / Study Product:	Outcome Attributed to SAE				Study Status			
1=Resolved (must have an end date) 2=Ongoing	1=Expected (refer to IB) 2=Unexpected (may need to fill out Unanticipated Problem (UP) form)	1=Mild 2=Moderate 3=Severe 4=Life threatening or permanently disabling 5=Fatal	1=Definite 2=Probable 3=Possible 4=Unlikely 5=Unrelated	1=Death:/ 1=Continuing in 2=Life Threatening 2=Withdrawn 3=Requires or Prolongs Inpatient Hospitalization 4=Persistent or Significant Disability or Incapacity 5=Congenital Anomaly/Birth Defect 6=Other Serious (Important Medical Events)				Study			
Description of Event (Diagnosis)		Organ System Classification: 1=HEENT, 2=cardiovascular, 3=abdomen, 4=lungs, 5=renal, 6=neurological, 7=musculoskeletal, 8=skin, 9=lymph nodes, 10=hematological, 11= Other	Start Date (//)	End Date (/)	Outcome Status	Expectedness	Severity	Relationship to Study/Study Product	Outcome Attributed to SAE	Study Status	Narrative added* (progress note)
1.											
2.											
3.											
4.											
5.											
* Narrative should inc	clude the following:	detailed description of eve	nt, problem, and/or pr	oduct use error, and r	elevant t	tests/labo	oratory o	ata, incl	uding dat	es	
PI Signature		D	)ate:								
RNC Signature	RNC Signature Date:										
Entered to eCRF	Initials										



FORM N	O. CNA04	13				
Is this un	anticipate	d problem specific to an individual subject?	☐ Yes	□No		
Acrostic I	dentifier:	(fill in if answer to above is "Yes")				
Study ID:	(fill in if a	answer to above is "Yes")				
Site: (fill	in if answ	er to above is "No")				
(Note: If the	e UP does r	not apply to an individual subject, the Acrostic Identifier and St	udy ID remain bla	nk)		
Date form	n complet	ed:/				
		Unanticipated Problem (UP) Rep	ort			
	-	y problem or event which in the opinion of the local researcher research procedures.	was unanticipated	, serious and at least		
These shou	ld be report	ed to the IRB within 10 working days.				
Date of the	Event:	<u></u>				
Date the si	te study te	am had knowledge of the Event://				
This Event	meets the	criteria for an unanticipated problem because:				
	1	<b>Unanticipated:</b> The event is unexpected in terms of nature, procedures described in the protocol, consent, etc. or given t studied.	•			
	Related: The event is related or possibly related to participation in the research. There is a reasonable possibility that the incident, experience, event, or outcome may have been caused by the procedures involved in research.					
	3	<b>Serious:</b> The event placed subjects or others at greater risk economic, or social harm) that was previously known or recoothers.				
		t meet all of the above criteria to be considered an unanti	cipated problem.			
Describe t	ne type of e	event:				
	Accidental	or unintentional change to the IRB-approved protocol that res	ulted in risk or has	s the potential to recur.		
		in the literature, safety monitoring report, or other findings incenefits of the research.	icating an unexpe	ected change to the risks or		
	Complaint	of a participant that indicates an unanticipated risk or which ca	annot be resolved	by the research staff.		
	A breach ir	n confidentiality that may involve risk to that individual or others	s (e.g. compromis	ed/stolen computer).		
	☐ Incarceration of a member of the research staff.					
Any other event that, in the opinion of the PI, constitutes an unanticipated risk.						
Description of the unanticipated problem:						
Provide a plan to prevent the problem from reoccurring in the future (indicate if protocol or consent modifications are required due to the event):						
Entered to	eCRF [	Initials				



#### **Cardiovascular Cell Therapy Research Network**

FOCUS Protocol Workbook

FORM NO.	.CNA044						
Acrostic Ide	entifier:						
Study ID:							
Date form	complete	ed:/					
		Protocol Deviation/Violation Report					
Date of the E	Date of the Event:/ Event has not yet occurred (exemption request)						
Date the site	study tea	am had knowledge of the Event:/					
This Event n	neets the	criteria for a protocol deviation/violation because:					
	1 1	The event resulted in an accidental or unintentional change to the IRB approved protocol and procedures without prior sponsor approval.					
	2	The event affected the participant's rights, safety, or welfare, or the integrity of the resultant data.					
	Note: The event must meet at least one of the above criteria to be considered a protocol deviation/violation.						
Describe ti	ie protoc	col deviation/violation:					
Explain wh	y or how	the deviation/violation occurred:					
Indicate the	e outcom	ne (PI's assessment of the outcome, comments, or determinations):					
Describe w	hat actio	on you have taken to prevent recurrence:					
PI Signatur	re	Date:					



RNC Signature	Date:					
Entered to eCRF Initials						
CCTRN Exer	nption/Waiver Documentation (DCC only)					
CCTRN Medical Officer or Designee Review:						
Action Taken:	☐ Granted ☐ Not Granted					
Waiver Acknowledgement:	☐ Received / Acknowledged					
DCC Signature	Date:					



FORM	1 NO. CNA048						
	tic Identifier:						
Study	Study ID:						
			Missing Form				
	Form Missi	ing:	Reason/Comment:	Date of this Report:			
	Baseline Risk Fa Cardiac Hx	actors & Other					
	Baseline Non Ca	ardio. Med. Hx					
	Baseline - Physi	cal Exam					
	Baseline - ECG						
	Baseline - Labs						
	Baseline - Qual.	of Life MLHF					
	Baseline - Qual.	of Life SF-36					
	Baseline - 6 min	ute walk test					
	Baseline - Holte	r					
	Medication aller	gies					
	Medication list						
	Bone Marrow As	spiration					
	Study Product In	njection					
	☐ Day of Injection - Phys. Exam						
	Day of Injection	- ECG					
	Day of Injection	- Holter					
	Day after Injection	on - Phys. Exan					
	Day after Injection	on - ECG					
	Day after Injection	on - Labs					
	Wk 1 - Physical	Exam					
	Wk 1 - ECG						
	Wk 1 - Holter						
	Wk 1 - Labs						
	Wk 4 - Physical	Exam					
	Wk 4 - Labs						
	Wk 4 - ECG						
	Wk 4 - Holter						
	Mo 3 - Physical	Exam					



FORN	I NO. CNA048			
Acros	tic Identifier:			
Study	ID:			
			Missing Form	
	Form Missi	ng:	Reason/Comment:	Date of this Report:
	Mo 3 - Labs			
	Mo 3 - Holter			
	Mo 3 - ECG			
	Mo 3 - Qual. of L	ife MLHF		
	Mo 3 - Qual. of L	ife SF-36		
	Mo 6 - Physical I	Exam		
	Mo 6 - Labs			
	Mo 6 - ECG			
	Mo 6 - Holter			
	Mo 6 - 6 minute	walk test		
	Mo 6 - Qual. of L	ife MLHF		
	Mo 6 - Qual. of L	ife SF-36		
	Mo 12 - Physical	l Exam		
	Mo 12 - Labs			
	Mo 12 - ECG			
	Mo 12 - Qual. of	Life MLHF		
	Mo 12 - Qual. of Life SF-36			
	Mo 24 - F/U Pho	ne Contact		
	Mo 36 - F/U Pho	ne Contact		
	Mo 48 - F/U Pho	ne Contact		
	Mo 60 - F/U Pho	ne Contact		
	End of Study			



Entered to eCRF

## Cardiovascular Cell Therapy Research Network FOCUS Protocol Workbook

FORM NO	O. CNA051				
Acrostic I	dentifier:				
Study ID:					
Date soul	rce form con	npleted://			
		E	nd of Study		
Date of fi	inal follow-ı	up study visit:/	/		
Reason f	or discharg	ge from the study:			
		Completed study			
		Withdrawn	Date:		
		Lost to follow-up	Date:		
		Screen Failure	Date:		
If "Withd	rawn", plea	se check the primary re	ason for withdr	awal:	
Reas	ons that req	uire follow-up:			
		Serious Adverse Event	(until resolved)	Event Number:	
		Pregnancy (1 year post b	oirth)	Event Number:	
Other Describe:			Describe:		
Reas	ons that DO	NOT require follow-up:			
		Death		Event Number:	
		Adverse Event		Event Number:	
		Withdrawal of consent			
		Protocol Deviation/Violat	ion		
		Investigator Discretion		Describe:	
		Sponsor Discretion		Describe:	
		Other		Describe:	
Diamag			. 4 -		
		lowing tasks are comple			
	All Informed	d Consents forms are prop	perly signed/date	ed and available	
		<b>G</b> .	•	in the CCTRN source document patient	
	binder; work	kbooks may be grouped b	y a visit with one	e signature per visit.	
	All source document data have been entered into the electronic CRF database				
	☐ All electronic CRFs have been submitted to the DCC				
				and found them to be in complete	
		with the source document			
			•	to missing, unclear, or incorrect entries),	
	ule authoriz	ed staff will supply approp	mate corrections	o.	
PI Signatu	ıre			Date:	

Initials \_\_\_\_\_



FORM NO. CNA005							
Acrostic Identifier:							
Study ID:							
Date source form co	mpleted: _	/	_/				
			Physical E	xam - Wee	k 1		
Date of Exam:/_	Date of Exam://						
☐ Informed consent	was revised	since study	y start date				
Date patient reconsente	Date patient reconsented:// Consent version:						
	Vital				NYHA	Class:	CCS Class:
Weight:		pounds .					
Temperature:	°F		auricle		<u> </u>		
Respirations:		ns/minute			<u> </u>		
Heart rate:	bea	ats/minute			/I	/ /A	∐ IV ∏ N/A
Blood Pressure:		 DBP	mmHg (sup	ine)		/A	IN/A
Review of Systems:							
Have changes occurred	since previou	ıs visit?	Yes No	☐ If no, ta	ıble is compl	ete.	
<u>Organs</u>		<u>Normal</u>	<u>Abnormal</u>	Not Examined	<u>Describe</u>		<u>escribe</u>
Skin							
HEENT							
Lungs							
CV							
Abdomen							
Lymph Nodes							
Musculoskeletal							
Neurological							
Other:							
Questions							
Has the patient experiend (If yes, complete AE form		lverse event	since last vis	sit?	Yes 🗆 N	No 🗆	
Have there been any signorisit? (If yes, please explant)			al findings s	ince last	Yes 🗆 N	No 🗆	
Have there been any cha (If yes, update medication	•	ications sinc	e last visit?		Yes 🔲 N	No 🗌	
Was the NIH Stroke Scale assessment completed? (If not done, or if result is evidence of deficit, please explain in comments)  No evidence of deficit   Evidence of deficit					<u> </u>		



EODMANO ONAGOE						
FORM NO. CNA005						
Acrostic Identifier:						
Study ID:						
Date source form co	mpleted:/					
Physical Exam - Week 1						
Questions						
Was a routine no contras abnormal, please explair	et Echo completed? (If not done, or if result in comments)	Yes No	Normal			
Has there been a change (If yes, please update me	e in nitrate usage since last visit? edication form)	Yes 🗌 No 🗌	N/A 🗌			
*Please remember to update medication form with inter-visit changes to medications						
Comments:						
Entered to eCRF	Initials					



FORM NO. CNA021					
Acrostic Identifier:					
Study ID:					
Date source form cor	mpleted:	//_			
	L	aboratory 1	ests - Week 1		
Date and time speci	men obtained	: Date: _	//	Time::	
<b>CBC</b> with Differentia	al Res	sult Unit	Normal I	Range	
WBC		K/m	m <sup>3</sup> 4.0-11.0	K/mm <sup>3</sup>	
RBC		M/m	m <sup>3</sup> 4.0-6.0 N	//mm <sup>3</sup>	
Hgb		gm/	dL 12.0-17.5	5 gm/dL	
Hct		%	33-53%		
MCV		fL	78-100 fl	L	
Platelets		K/m	m <sup>3</sup> 135-450	K/mm <sup>3</sup>	
WBC Differential					
Neutrophilis		%	36-74%		
Lymphocytes		%	12-45%		
Monocytes		%	0-13%		
Eosinophils		%	0-8%		
Basophils		%	< 3.0%		
Cardiac Markers (Eit	her Troponin T o	r Troponin I s	should be comple	ted, NOT both)	
Troponin T		ng/n	nl 0.0-10 ท <i>ู</i>	g/ml	
Troponin I		ng/n	nl 0.0-100 r	ng/ml	
СК		U/L	25-10,00	00 U/L	
CK-MB		ng/r	nl 0.0-250 r	ng/ml	
Chem-8					
BUN		mg/	dL 5-26 mg/	/dL	
Creatinine		mg/	dL 0.4-1.5 m	ng/dL	
Liver Function Tests	s				
Bilirubin-Total		mg/	dL 0.0-1.5 m	ng/dL	
Bilirubin-Direct		mg/	dL 0.0-0.4 m	ng/dL	
Total Protein		g/dL	. 6.0-8.5 g	/dL	
Alk Phos		U/L	30-150 L	J/L	
ALT		U/L	0-50 U/L		
AST		U/L	0-42 U/L		



FORM NO. CNA021						
Acrostic Identifier:						
Study ID:						
Date source form con	npleted:	/	_/			
		Laborat	tory Tests	s - Week 1		
Other Tests						
BNP			pg/ml	0-100 pg/ml		
hsCRP			mg/L	0.0-40 mg/L		
Comments:			-			
PI Signature					Date:	
Entered to eCRF		Init	ials			



Entered to eCRF

## Cardiovascular Cell Therapy Research Network FOCUS Protocol Workbook

FORM NO. CNA023				
Acrostic Identifier:				
Study ID:				
Date source/workbook completed://				
Holter Data Fo	orm - Week 1			
Date procedure started://	Predominant Rhythm: (mutually exclusive)			
Total recording time:::	Sinus Rhythm Junctional Rhythm			
General:	Paced Rhythm Ectopic Atrial Rhythm			
Total beats/QRS Complexes: beats	Atrial Flutter / Fibrillation			
Paced beats: beats	Heart Rates:			
Pauses/Longest RR Interval (> 2 secs):	Minimum:beats/min. @:			
Longest pause was seconds @:	Average:beats/min.			
Total number of pauses:	Maximum: beats/min. @:			
Ventricular Arrhythmia Summary:	Supraventricular Arrhythmia Summary:			
Single/PVC: beats	Single/PAC: beats			
Couplets:	Couplets:			
Total number of NSVT Runs (≥ 3 beats)	Total number of SVT Runs			
Number of beats in longest NSVT run	Number of beats in longest SVT run			
Total number of sustained ventricular tachycardia runs	Intermittent Atrial Fibrillation / Atrial Flutter:			
(≥ 30 secs)	☐ Yes ☐ No			
	If yes, total no. of episodes			
	If yes, min.secs (duration of longest			
	episode)			
AV Block: (Choose all that apply)				
☐ Transient AV block, 2nd degree-Mobitz type 1 (Wenkebach)	□ N/A			
total no. of episodes duration	on of longest episode (secs)			
☐ Transient AV block, 2nd degree-Mobitz type 2 ☐ N/A				
total no. of episodes duration of longest episode (secs)				
☐ Transient AV block, 3rd degree ☐ N/A				
total no. of episodes duration	on of longest episode (secs)			
Comments:				
PI Signature:	Date:			

Initials \_\_\_\_\_



FORM NO. CNA024							
Acrostic Identifier:							
Study ID:							
Date source form completed://							
ECG - Week 1							
Date of Procedure:/ Time:	:						
PR interval: 0 sec QRS interval: 0 se	ec QT interval: 0 sec HR: bpm						
☐ ECG NORMAL ☐ ECG NOT NORMAL							
Note: If you select "ECG NORMAL", you are done wit	th this form.						
Rhythm: (Check all that apply)							
normal sinus rhythm	ventricular demand pacemaker (VVI)						
sinus arrhythmia	atrial pacemaker						
sinus bradycardia (<60 bpm)	dual chamber pacemaker (DDD)						
sinus tachycardia (>100 bpm)	wandering pacemaker						
atrial fibrillation	accelerated idioventricular rhythm						
atrial flutter	atrial premature complexes						
multifocal atrial tachycardia	ventricular premature complexes (PVCs)						
supraventricular tachycardia	ventricular couplets						
junctional tachycardia	iunctional rhythm						
ventricular bigeminy	ventricular fibrillation						
ectopic atrial rhythm							
ventricular tachycardia (< 30 seconds) > 12	20 bpm (must fill in a & b if this box is checked)						
If ventricular tachycardia, please complete:							
	erage Rate: bpm						
If patient is on pacemaker (as indicated above), c							
☐ 100% paced ☐ intermittently pace	ed N/A (If 100% paced, do not complete rest	of form)					
AV Conduction Abnormalities: (Choose one)		NONE					
AV block, 1st degree							
AV block, 2nd degree Mobitz type 1 (Wenk	ebach)						
AV block, 2nd degree Mobitz type 2							
AV block, 3rd degree							
Abnormalities of P wave: (Choose all that apply)		NONE					
Left atrial enlargement	Right atrial enlargement						
Abnormalities of QRS axis: (Choose one)		NONE					
Left axis deviation(> -30°)	Right axis deviation (> +100°)						
QRS voltage abnormalities: (Choose all that apply)		NONE					
Low voltage	Right ventricular hypertrophy						
Left ventricular hypertrophy							



FORM NO. CNA024					
Acrostic Identifier:					
Study ID:					
Date source form completed:/	/				
		ECC	G - Week 1	1	
Intraventricular conduction abnormalities	: (Choos	se all	that apply	')	ONE
Right bundle branch block, com	plete		Left bur	ndle branch block, complete	
Right bundle branch block, inco	mplete		Left bur	ndle branch block, incomplete	
Left anterior fascicular block			Nonspe	ecific intraventricular conduction disturbance	
Left posterior fascicular block					
			For eac	ch "Yes" response, check all locations that apply:	
Are Q waves present?	Υ		N 🔲	Anterior Lateral Inferior	
Is ST segment elevation present?	Υ		N 🗌	Anterior Lateral Inferior	
Is ST segment depression present?	Υ		N 🗌	Anterior Lateral Inferior	
Is T wave inversion present?	Υ		N 🗌	Anterior Lateral Inferior	
Is there evidence of posterior infarction?	Y		N 🗆	$ \begin{array}{c cccc} \text{Pathologic} & R & \text{Abn. ST} & & \text{Abn. ST} \\ \text{wave} & & V_1, \text{ depression} & & \text{elevation} \\ V_2 & \square & & V_1, V_2 & \square & & V_1, V_2 & \square \\ \end{array} $	
Is there evidence of RV infarction (right precordial leads)?	Υ		N 🗆	N/A 🗆	
Are there nonspecific ST and/or T wave abnormalities present?	Υ		N 🖂		
Comments:					
PI Signature				Date:	
Entered to eCRE Initials					



FORM NO. CNA005								
Acrostic Identifier:								
Study ID:								
Date source form completed:/								
Physical Exam - Week 4								
Date of Exam:/_			s outside tir		, , , , , , , , , , , , , , , , , , ,	Reason:		
☐ Informed consent was revised since study start date								
Date patient reconsent			Consent	version:	ND///A	01	000.01	
Woight	Vital				NYHA		CCS Class:	
Weight:		pounds						
Temperature:	°F	loral	auricle					
Respirations: Heart rate:		ns/minute ats/minute					IV	
Heart rate.		ats/minute				//A	N/A	
Blood Pressure:	/ SBP	 DBP	mmHg (sup	ine)				
Review of Systems:								
Have changes occurred	since previou	ıs visit?	Yes No	☐ If no, ta	able is comp	ete.		
<u>Organs</u>		<u>Normal</u>	<u>Abnormal</u>	Not Examined		<u>D</u>	<u>escribe</u>	
Skin								
HEENT								
Lungs								
CV								
Abdomen								
Lymph Nodes								
Musculoskeletal								
Neurological								
Other:								
Questions								
Has the patient experienced a new adverse event since the last follow-up visit? (If yes, complete AE form)								
Have there been any significant changes in physical findings since the last follow-up visit? (If yes, please explain in comments)								
Have there been any changes to medications since the last follow-up visit? (If yes, update medication form)  Yes No								



Entered to eCRF

Initials \_\_\_\_\_

FORM NO. CNA005			
Acrostic Identifier:			
Study ID:			
Date source form co	mpleted://		
	Physical Exam - Week	k 4	
Questions			
	le assessment completed? (If not done, or if cit, please explain in comments)	Yes No	No evidence of deficit   Evidence of deficit
one 10 ml venous blood drawn to ship to the biore no, please explain in the	· · · · · · · · · · · · · · · · · · ·	Yes  No	
Has there been a change (If yes, please update me	e in nitrate usage since the last follow-up visit? edication form)	Yes  No	N/A 🗌
	pdate medication form with inter-visit changes	to medications	
Comments:			
_			



FORM NO. CNA021							
Acrostic Identifier:							
Study ID:							
Date source form cor	npleted:/	/					
	Labo	ratory Tests	s - Week 4				
Date and time specimen obtained: Date:/ Time: ::							
<b>CBC</b> with Differentia	al Result	Unit	Normal Range				
WBC		K/mm <sup>3</sup>	4.0-11.0 K/mm <sup>3</sup>				
RBC		M/mm <sup>3</sup>	4.0-6.0 M/mm <sup>3</sup>				
Hgb		gm/dL	12.0-17.5 gm/dL				
Hct		%	33-53%				
MCV		fL	78-100 fL				
Platelets		K/mm <sup>3</sup>	135-450 K/mm <sup>3</sup>				
WBC Differential							
Neutrophilis		%	36-74%				
Lymphocytes		%	12-45%				
Monocytes		%	0-13%				
Eosinophils		%	0-8%				
Basophils		%	< 3.0%				
Cardiac Markers (Eit	her Troponin T or Tr	oponin I shoul	d be completed, NOT both)				
Troponin T		ng/ml	0.0-10 ng/ml				
Troponin I		ng/ml	0.0-100 ng/ml				
СК		U/L	25-10,000 U/L				
CK-MB		ng/ml	0.0-250 ng/ml				
Chem-8							
BUN		mg/dL	5-26 mg/dL				
Creatinine		mg/dL	0.4-1.5 mg/dL				
Liver Function Tests	s						
Bilirubin-Total		mg/dL	0.0-1.5 mg/dL				
Bilirubin-Direct		mg/dL	0.0-0.4 mg/dL				
Total Protein		g/dL	6.0-8.5 g/dL				
Alk Phos		U/L	30-150 U/L				
ALT		U/L	0-50 U/L				
AST		U/L	0-42 U/L				



FORM NO. CNA021				
Acrostic Identifier:				
Study ID:				
Date source form con	npleted:	/	/	
		Laborat	ory Tests	s - Week 4
Other Tests				
BNP			pg/ml	0-100 pg/ml
hsCRP			mg/L	0.0-40 mg/L
Pregnancy Test (wor childbearing potential Not applicable				Negative (urine) < 5.0 mU/ml (quantitative blood)
Comments:				
PI Signature				Date:
Entered to eCRF		Initi	als	



FORM NO. CNA023						
Acrostic Identifier:						
Study ID:						
Date source/workbook completed://						
Holter Data Form - Week 4						
Date procedure started://	Predominant Rhythm: (mutually exclusive)					
Total recording time:::	☐ Sinus Rhythm ☐ Junctional Rhythm					
General:	☐ Paced Rhythm ☐ Ectopic Atrial Rhythm					
Total beats/QRS Complexes: beats	Atrial Flutter / Fibrillation					
Paced beats: beats	Heart Rates:					
Pauses/Longest RR Interval (> 2 secs):	Minimum: beats/min. @ :					
Longest pause was seconds @:	Average:beats/min.					
Total number of pauses:	Maximum: beats/min. @:					
Ventricular Arrhythmia Summary:	Supraventricular Arrhythmia Summary:					
Single/PVC: beats	Single/PAC: beats					
Couplets:	Couplets:					
Total number of NSVT Runs (≥ 3 beats)	Total number of SVT Runs					
Number of beats in longest NSVT run	Number of beats in longest SVT run					
Total number of sustained ventricular tachycardia runs	Intermittent Atrial Fibrillation / Atrial Flutter:					
(≥ 30 secs)	☐ Yes ☐ No					
	If yes, total no. of episodes					
	If yes, min.secs (duration of longest					
	episode)					
AV Block: (Choose all that apply)						
☐ Transient AV block, 2nd degree-Mobitz type 1 (Wenkebach)	□ N/A					
total no. of episodes duration of longest episode (secs)						
☐ Transient AV block, 2nd degree-Mobitz type 2 ☐ N/A						
total no. of episodes duration of longest episode (secs)						
☐ Transient AV block, 3rd degree ☐ N/A	☐ Transient AV block, 3rd degree ☐ N/A					
·	on of longest episode (secs)					
Comments:						

PI Signature: \_\_\_\_\_ Date: \_\_\_\_\_



FORM NO. CNA024		
Acrostic Identifier:		
Study ID:		
Date source form completed://		
EC	CG - Week 4	
Date of Procedure:/ Time: _	:	
PR interval: 0 sec QRS interval: 0 se	ec QT interval: 0 sec HR: bpm	
☐ ECG NORMAL ☐ ECG NOT NORMAL		
Note: If you select "ECG NORMAL", you are done wit	th this form.	
Rhythm: (Check all that apply)		
normal sinus rhythm	ventricular demand pacemaker (VVI)	
sinus arrhythmia	atrial pacemaker	
sinus bradycardia (<60 bpm)	dual chamber pacemaker (DDD)	
sinus tachycardia (>100 bpm)	wandering pacemaker	
atrial fibrillation	accelerated idioventricular rhythm	
atrial flutter	atrial premature complexes	
multifocal atrial tachycardia	ventricular premature complexes (PVCs)	
supraventricular tachycardia	ventricular couplets	
junctional tachycardia	☐ junctional rhythm	
ventricular bigeminy	ventricular fibrillation	
ectopic atrial rhythm		
ventricular tachycardia (< 30 seconds) > 12	0 bpm (must fill in a & b if this box is checked)	
If ventricular tachycardia, please complete:		
a. Length: complexes b. Avei	rage Rate: bpm	
If patient is on pacemaker (as indicated above), ch	hoose level of pacing:	
☐ 100% paced ☐ intermittently paced	d N/A (If 100% paced, do not complete rest of	form)
AV Conduction Abnormalities: (Choose one)		NONE
AV block, 1st degree		
AV block, 2nd degree Mobitz type 1 (Wenke	ebach)	
AV block, 2nd degree Mobitz type 2		
AV block, 3rd degree		
Abnormalities of P wave: (Choose all that apply)		NONE
Left atrial enlargement	Right atrial enlargement	
Abnormalities of QRS axis: (Choose one)		NONE
Left axis deviation(> -30°)	Right axis deviation (> +100°)	
QRS voltage abnormalities: (Choose all that apply)		NONE
Low voltage	Right ventricular hypertrophy	
Left ventricular hypertrophy		



FORM NO. CNA024							
Acrostic Identifier:							
Study ID:							
Date source form completed:	//						
		EC	G - Week 4	1			
Intraventricular conduction abnorr	nalities: (Choo	se al	I that apply	)			NONE
Right bundle branch blo	ck, complete		Left bundle branch block, complete				
Right bundle branch blo	ck, incomplete		Left bur	ndle branch bloc	k, incomplete		
Left anterior fascicular b	lock		Nonspe	cific intraventric	ular conduction	n disturbance	
Left posterior fascicular	block						
			For eac	h "Yes" respons	e, check all lo	cations that a	pply:
Are Q waves present?	Υ		N 🗌	Anterior	Lateral	Inferior	
Is ST segment elevation present?	Y		N 🗌	Anterior	Lateral	Inferior	
Is ST segment depression present?	Y		N 🗌	Anterior	Lateral	Inferior	
Is T wave inversion present?	Υ		N 🗌	Anterior	Lateral	Inferior	
Is there evidence of posterior infarction	on? Y		N 🗆		Abn. ST depression V <sub>1</sub> , V <sub>2</sub>	Abn. ST elevation $V_1, V_2$	
Is there evidence of RV infarction (rig precordial leads)?	ht Y		N 🗆	N/A □			
Are there nonspecific ST and/or T waabnormalities present?	ve Y		N 🗆				
Comments:							
PI Signature					Date:		
Entered to eCRF							