Persons using assistive technology may not be able to fully access information in this file. For assistance, e-mail biolincc@imsweb.com. Include the Web site and filename in your message.

FORM NO. CNA006	
Acrostic Identifier:	
Study ID:	
Date source form completed: _____/_____/_____	

Physical Exam - *Day of Injection*

Date of Exam: _____/_____/_____	☐ **Visit is outside time window**	**Reason:**

☐ **Informed consent was revised since study start date**

Date patient reconsented: ___/___/____ **Consent version:**

Vital Signs		**NYHA Class:**	**CCS Class:**
Weight:	_____ pounds	☐ I	☐ I
Temperature:	_____°F ☐ oral ☐ auricle	☐ II	☐ II
Respirations:	__ __ breaths/minute	☐ III	☐ III
Heart rate:	__ __ __ beats/minute	☐ IV	☐ IV
Blood Pressure:	__ __ __ / __ __ __ mmHg (supine) SBP DBP	☐ N/A	☐ N/A

Review of Systems:

Have changes occurred since previous visit? Yes ☐ No ☐ If no, table is complete.

Organs	Normal	Abnormal	Not Examined	Describe
Skin	☐	☐	☐	
HEENT	☐	☐	☐	
Lungs	☐	☐	☐	
CV	☐	☐	☐	
Abdomen	☐	☐	☐	
Lymph Nodes	☐	☐	☐	
Musculoskeletal	☐	☐	☐	
Neurological	☐	☐	☐	
Other: _____	☐	☐	☐	

Questions:

Has the patient experienced any new adverse events? (If yes, complete AE form)	Yes ☐ No ☐
Have there been any significant changes in physical findings since last visit? (If yes, please explain in comments)	Yes ☐ No ☐
Have there been any changes to medications? (If yes, update medication form)	Yes ☐ No ☐

FORM NO. CNA006	
Acrostic Identifier:	
Study ID:	
Date source form completed: _____/_____/_____	

Physical Exam - *Day of 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 ☐
Was the baseline MRI (if applicable) completed and results sent to the Core Lab? (If no, please explain in Comments)	Yes ☐ No ☐	N/A ☐
Was the routine no contrast transthoracic Echo performed immediately after product delivery while in the coronary angiography recovery area to determine the presence of a pericardial effusion? (If not done, or if result abnormal, please explain in comments)	Yes ☐ No ☐	Normal ☐ Abnormal ☐
Was the routine no contrast Echo completed 4-6 hours post procedure Lab? (If not done, or if result abnormal, please explain in comments)	Yes ☐ No ☐	Normal ☐ Abnormal ☐
Were five 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? (If no, please explain in the Comments) **Verify patient consented to Biorepository before you draw Biorepository bloods.**	Yes ☐ No ☐	
Has there been a change in nitrate usage since last visit? (If yes, please update medication form)	Yes ☐ No ☐	N/A ☐
***Please remember to update medication form with inter-visit changes to medications**		
Comments:		

Entered to eCRF ☐ Initials _____

FORM NO. CNA029	
Acrostic Identifier:	
Study ID:	
Date source form completed: _____/_____/_____	
Bone 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 adverse event during the procedure? (If yes, complete AE or SAE form)	Yes ☐ No ☐
Were concomitant medications given? (If yes, add to medication form)	Yes ☐ No ☐
Comments:	

Entered to eCRF ☐ Initials _____

FORM NO. CNA031				
Acrostic Identifier:				
Study ID:				
Date source form completed: _____/_____/_____				
Vital Signs Pre-Procedure (Pre-Study Product Injection)				
Date: _____/_____/_____ Time: __ __:__ __				
Temperature:	__ __.__°F ☐ oral ☐ auricle			
Respirations:	__ __ breaths/min			
Heart rate:	__ __ __ beats/min			
Blood Pressure:	__ __ __ / __ __ __ mmHg (supine) SBP DBP			
Study Product Injection 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. CNA031

Acrostic Identifier:

Study ID:

Date source form completed: _____/_____/_____

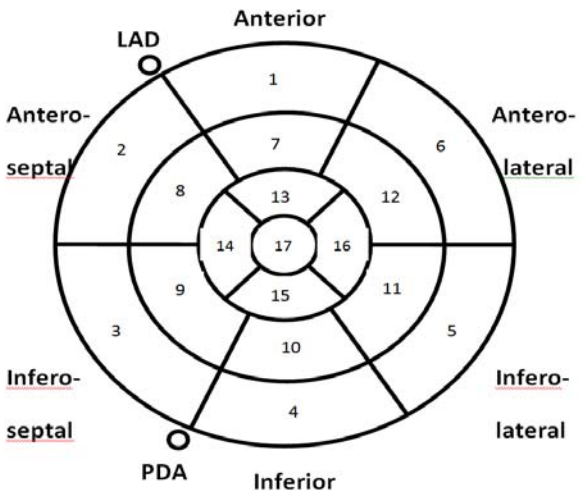
Mapping / Injection Information

Number of Segments of testing device? ☐ 12 ☐ 17

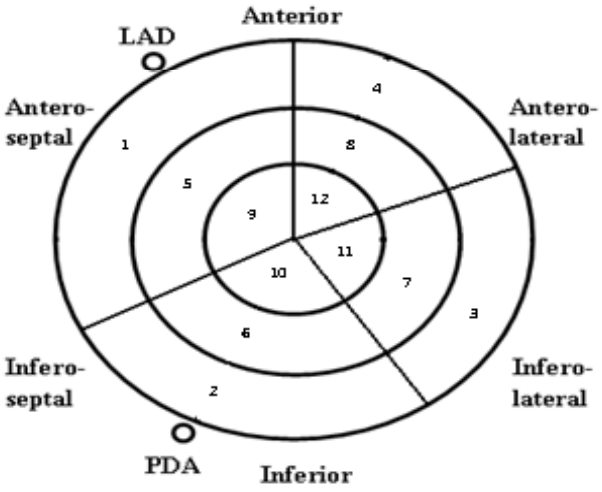
Mapping Segment	UPV	LLS	# Injections / segment
1	_____mV	_____ %	_____
2	_____mV	_____ %	_____
3	_____mV	_____ %	_____
4	_____mV	_____ %	_____
5	_____mV	_____ %	_____
6	_____mV	_____ %	_____
7	_____mV	_____ %	_____
8	_____mV	_____ %	_____
9	_____mV	_____ %	_____
10	_____mV	_____ %	_____
11	_____mV	_____ %	_____
12	_____mV	_____ %	_____
13	_____mV	_____ %	_____
14	_____mV	_____ %	_____
15	_____mV	_____ %	_____
16	_____mV	_____ %	_____
17	_____mV	_____ %	_____

17 segment (TX)

Diagram of Mapping Segments



12 segment (CL, FL, MN, VN)



Total Mapping Points: _____ Sum of Injection Points: _____

FORM NO. CNA031

Acrostic Identifier:

Study ID:

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 ☐ No ☐	_____mV	Yes ☐ No ☐	_____ ml	Yes ☐ No ☐	☐
10		_____ mm	Yes ☐ No ☐	_____mV	Yes ☐ No ☐	_____ ml	Yes ☐ No ☐	☐
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 Injections: _____ Total Volume: _____

FORM NO. CNA031			
Acrostic Identifier:			
Study ID:			
Date source form completed: _____/_____/_____			
Vital Signs Post-Procedure (Post-Study Product Injection)			
Date: _____/_____/_____ Time: __ __:__ __			
Temperature:	__ __.__°F ☐ oral ☐ auricle		
Respirations:	__ __ breaths/minute		
Heart rate:	__ __ __ beats/minute		
Blood Pressure:	__ __ __ / __ __ __ mmHg (supine) SBP DBP		
Questions			
1. Was there any difficulty with mapping? (If yes, please explain in Comments)		Yes ☐	No ☐
2. Did the patient experience an adverse event during mapping? (If yes, complete AE or SAE form)		Yes ☐	No ☐
3. Were all 15 injections given? (If no, please explain in Comments)		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)		Yes ☐	No ☐
5. Was the procedure 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 concomitant medications given? (If yes, add to Medication form)		Yes ☐	No ☐
Comments:			

Entered to eCRF ☐ Initials _____

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 - *Day of Injection*

Date procedure started: _____/_____/_____

Total recording time: __ __:__ __

General:

Total beats/QRS Complexes: __ __ __ __ __ __ beats

Paced beats: __ __ __ __ __ __ beats

Pauses/Longest RR Interval (> 2 secs):

Longest pause was __ __ seconds @ __ __:__ __

Total number of pauses: __ __ __

Predominant Rhythm: *(mutually exclusive)*

☐ Sinus Rhythm ☐ Junctional Rhythm

☐ Paced Rhythm ☐ Ectopic Atrial Rhythm

☐ Atrial Flutter / Fibrillation

Heart Rates:

Minimum: __ __ __beats/min. @ __ __:__ __

Average: __ __ __beats/min.

Maximum: __ __ __beats/min. @ __ __:__ __

Ventricular Arrhythmia Summary:

Single/PVC: __ __ __ __ __ __ beats

Couplets: __ __ __ __ __ __

Total number of NSVT Runs (≥ 3 beats) __ __ __

Number of beats in longest NSVT run __ __ __

Total number of sustained ventricular tachycardia runs (≥ 30 secs) __ __ __

Supraventricular Arrhythmia Summary:

Single/PAC: __ __ __ __ __ __ beats

Couplets: __ __ __ __ __ __

Total number of SVT Runs __ __ __

Number of beats in longest SVT run __ __ __

Intermittent Atrial Fibrillation / Atrial Flutter:

☐ 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

__ __ __ total no. of episodes __ __ __ __ __ duration of longest episode (secs)

Comments:

PI Signature: _____ Date: _____

Entered to eCRF ☐ Initials _____

FORM NO. CNA024	
Acrostic Identifier:	
Study ID:	

Date source form completed: _____/_____/_____

ECG - *Day of Injection*

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
- ☐ sinus arrhythmia
- ☐ sinus bradycardia (<60 bpm)
- ☐ sinus tachycardia (>100 bpm)
- ☐ atrial fibrillation
- ☐ atrial flutter
- ☐ multifocal atrial tachycardia
- ☐ supraventricular tachycardia
- ☐ junctional tachycardia
- ☐ ventricular bigeminy
- ☐ ectopic atrial rhythm
- ☐ ventricular demand pacemaker (VVI)
- ☐ atrial pacemaker
- ☐ dual chamber pacemaker (DDD)
- ☐ wandering pacemaker
- ☐ accelerated idioventricular rhythm
- ☐ atrial premature complexes
- ☐ ventricular premature complexes (PVCs)
- ☐ ventricular couplets
- ☐ junctional rhythm
- ☐ ventricular fibrillation
- ☐ 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 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 enlargement

Abnormalities of QRS axis: (Choose one) ☐ **NONE**

- ☐ Left axis deviation(> -30º)
- ☐ Right axis deviation (> +100º)

QRS voltage abnormalities: (Choose all that apply) ☐ **NONE**

- ☐ Low voltage
- ☐ Left ventricular hypertrophy
- ☐ Right ventricular hypertrophy

FORM NO. CNA024	
Acrostic Identifier:	
Study ID:	

Date source form completed: _____/_____/_____

ECG - *Day of Injection*

Intraventricular conduction abnormalities: (Choose all that apply) ☐ **NONE**

- ☐ Right bundle branch block, complete
- ☐ Right bundle branch block, incomplete
- ☐ Left anterior fascicular block
- ☐ Left posterior fascicular block
- ☐ Left bundle branch block, complete
- ☐ Left bundle branch block, incomplete
- ☐ Nonspecific intraventricular conduction disturbance

			For each "Yes" response, check all locations that apply:		
Are Q waves present?	Y ☐	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?	Y ☐	N ☐	Anterior ☐	Lateral ☐	Inferior ☐
Is there evidence of posterior infarction?	Y ☐	N ☐	Pathologic wave V_2 ☐	R V_1, Abn. ST depression V_1, V_2 ☐	Abn. ST elevation V_1, V_2 ☐
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 _____

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 Biorepository blood draws (if consented) Bone Marrow Aspiration Baseline cMRI (if applicable) (core) Cell Processing Cell Processing - Post Release Study Product Infusion ECG Holter Routine Echo immediately post procedure Routine Echo 4-6 hrs post procedure	**SPI + 14 days**
Day after Injection	**SPI + 1 day**
Day after Injection PE Biorepository blood draws (if consented) Labs ECG	
1 Week	**SPI + 7 days +/- 2 days**
PE Labs Holter Routine Echo ECG	
4 Weeks	**SPI + 30 days +/- 5 days**
PE Labs Biorepository blood draws (if consented) ECG Holter	

FORM NO. CNA045	
Acrostic Identifier:	
Study ID:	
Schedule of Procedures 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	

FOCUS Labs by Visit Time 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_2				
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*

*** Other Tests/Pregnancy: women of childbearing potential**

**** Day After Infusion/Cardiac Enzymes: collected every 8 hours post infusion**

FORM NO. CNA099		
Date form completed: ____/____/____		
Screening / Demographics		
Last Name:		
First Name:		
Middle Initial:		
Consent signed ☐	Biorepository consent signed	☐ Yes ☐ No
Date of Birth	____/____/____	
Sex	M ☐ F ☐	
Hispanic	N ☐ Y ☐	
Race (choose one):		
White		☐
Black or African American		☐
Asian		☐
Native Hawaiian or Other Pacific Islander		☐
American Indian or Alaska Native		☐
Other		☐
Marital Status (choose one):		
Married		☐
Living with a partner		☐
Single/never married		☐
Widowed		☐
Divorced		☐
Separated		☐

Entered to eCRF ☐ Initials _____

FORM NO. CNA001	
Acrostic Identifier:	
Study ID:	
Date source form 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. Maximal medical therapy for anginal symptoms is defined as a medical regimen that includes the maximal tolerated dose of at least two anti-angina 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. Maximal medical therapy for heart failure symptoms 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 _____/_____/_____.
Y	**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^3.

FORM NO. CNA001	
Acrostic Identifier:	
Study ID:	
Date source form completed: _____/_____/_____	

Eligibility Criteria		
Y	**N**	**Exclusion Criteria continued (Must answer No to all questions to be eligible)**
☐	☐	WBC < 2 K/mm^3.
☐	☐	Revascularization within 30 days.
☐	☐	TIA or stroke within 60 days of study enrollment.
☐	☐	ICD shock within 30 days of baseline screening.
☐	☐	Presence of sustained ventricular tachycardia (30 or more seconds) on 24 hour Holter monitor or ECG performed during screening period.
☐	☐	A bleeding diathesis defined as an INR ≥ 2.0 in the absence of warfarin therapy.
☐	☐	A history of malignancy in the last 5 years excluding basal cell carcinoma that has been surgically removed with proof of surgical clean margins.
☐	☐	Has a known history of HIV, or has active Hepatitis B or active Hepatitis C.
☐	☐	Any previous transplant requiring immunosuppressive medication.
☐	☐	A high-risk acute coronary syndrome (ACS) or a myocardial infarction in the month prior to evaluation. (ACS is defined as the presence of chest pain characteristic for angina, dynamic electrocardiography changes of ST segment depression or elevation and/or serum elevation of troponin I or T > 3X ULN (according to local laboratory)).
☐	☐	A left ventricular wall thickness of <8 mm (by echocardiogram) of the infero-lateral wall at the target site for cell injection.
☐	☐	Inability to walk on a treadmill except for class IV angina patients who will be evaluated separately. (If only reason patient is unable to walk on treadmill is class IV angina, then patient will be included.)
☐	☐	Potential patients enrolled in an investigational device or drug study within the previous 30 days.
☐	☐	Hepatic dysfunction, as defined as aspartate aminotransferase (AST) and /or alanine aminotranferase (ALT) > 1.5X ULN prior to study entry.
☐	☐	Chronic renal insufficiency as defined as a serum creatinine > 2.5 mg/dL or requires dialysis.
☐	☐	Any other condition that in the judgment of the investigator would be a contraindication to enrollment or follow-up.
Y	**N**	**Special Criteria (Must answer No to first question OR Yes to both to be eligible)**
☐	☐	Does the patient meet the following criteria: LVEF ≤ 35%; sinus rhythm; NYHA functional class III or ambulatory class IV symptoms despite recommended, optimal medical therapy; and has cardiac 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 completed: _____/_____/_____	

Eligibility Criteria

☐ This patient became ineligible during the screening process; not all data were collected to answer every question; all questions addressed with the patient have been 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: _____/_____/_____					
Baseline Risk Factors					
Diabetes	No ☐	Type I ☐	Type II ☐		
Diabetes Treatment:	Oral Hypoglycemics ☐	Insulin ☐	Neither ☐		
Hypertension	No ☐	Yes ☐			
Hypertension Treatment:	1 medication ☐	2 or more meds ☐	No medication ☐		
Hyperlipidemia	No ☐	Yes ☐			
Hyperlipidemia Treatment:	Diet controlled ☐	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 (males <55 females <65)	No ☐	Yes ☐	Unknown ☐		
Angina Date most recent: ___/___/__	No ☐	Stable ☐	Unstable ☐		
Carotid Disease, asymptomatic	No ☐	Yes ☐			
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 ☐	tricuspid ☐	
History of Aneurysm	No ☐	Yes ☐			

FORM NO. CNA003					
Acrostic Identifier:					
Study ID:					
Date source form completed: _____/_____/_____					
Baseline Risk Factors					
History of Stroke	No ☐		current deficit ☐	completely resolved ☐	
History of PVD	No ☐		Yes ☐		
History of arrhythmias	No ☐		Yes ☐	Unknown ☐	If yes, type:_____ Date of onset: ___/___/___
History of bleeding diathesis	No ☐		Yes ☐	Unknown ☐	If yes, please describe in Comments
Obese or history of obesity	No ☐		Yes ☐		
Smoking	Never ☐		Previous ☐ Yr stopped: _____	Current ☐ packs/day: __	
Other Cardiac History					
Please describe interventions in the Comments section including number of interventions (if same procedure done more than once) and the specific vessel affected.					
Prior to this hospitalization, have you been hospitalized 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 coronary interventions:					
Procedure:					**Date:**
1.					___/___/_____
2.					___/___/_____
3.					___/___/_____
4.					___/___/_____
5.					___/___/_____
Questions:					
If female, is patient of child bearing potential?	No ☐		Yes ☐	N/A ☐	If no, check one: post menopausal ☐ surgically sterile ☐

FORM NO. CNA003	
Acrostic Identifier:	
Study ID:	
Date source form completed: _____/_____/_____	
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:	

Entered to eCRF ☐ 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			
Acrostic Identifier:			
Study ID:			
Date source form completed: _____/_____/_____			
Medication Allergies			
Drug Allergies	NKDA ☐	Yes ☐	Please list:

FORM NO. CNA011								
Acrostic Identifier:								
Study ID:								
Date source form completed: _____/_____/_____								
Medications								
	Medication 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						☐		
Comments								

Entered to eCRF ☐ Initials _____

Medication eCRF drop down list:

Drug Classes	Units	Frequency
Allopurinol	CAP=capsule	BID=twice daily
Angiotensin converting enzyme inhibitors	g=gram	ONCE=one dose
Antianginal	GR=grain	per hour
Antiarrhythmics	GTT=drop	per minute
Antibiotics	IU=international units	PRN=as needed
Anticoagulants	mg=milligram	QD=once daily
Antiplatelet agents (non-aspirin)	mL=milliliter	QID=4 times/day
Aspirin	oz=ounce	QOD=everyother day
Beta blockers	PUF=puff	TID=3 times/day
Calcium channel blockers	SPY=spray/squirt	OTH=other (specify)
Cholesterol-lowering agents	SUP=suppository	
Digitalis	TAB=tablet	
Diuretics	TBS=tablespoon	
Inotrope	TSP=teaspoon	
Insulin	U=units	
Nitrates	ug=microgram	
Non-ACE inhibitor arterial vasodilators (e.g. hydralazine)	uL=microliter	
Non-insulin hormones	UNK=unknown	
Oral hypoglycemics	OTH=other (specify)	
Other antihypertensives		
Pain medications		
Potassium		
Supplements		
Sympathetic blockers		
Tranquilizers		
Vaccines		
Vasodilators		
Others		

FORM NO. CNA024	
Acrostic Identifier:	
Study ID:	

Date source form completed: _____/_____/_____

ECG - *Baseline*

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
- ☐ sinus arrhythmia
- ☐ sinus bradycardia (<60 bpm)
- ☐ sinus tachycardia (>100 bpm)
- ☐ atrial fibrillation
- ☐ atrial flutter
- ☐ multifocal atrial tachycardia
- ☐ supraventricular tachycardia
- ☐ junctional tachycardia
- ☐ ventricular bigeminy
- ☐ ectopic atrial rhythm
- ☐ ventricular demand pacemaker (VVI)
- ☐ atrial pacemaker
- ☐ dual chamber pacemaker (DDD)
- ☐ wandering pacemaker
- ☐ accelerated idioventricular rhythm
- ☐ atrial premature complexes
- ☐ ventricular premature complexes (PVCs)
- ☐ ventricular couplets
- ☐ junctional rhythm
- ☐ ventricular fibrillation
- ☐ 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 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 enlargement

Abnormalities of QRS axis: (Choose one) ☐ **NONE**

- ☐ Left axis deviation(> -30º)
- ☐ Right axis deviation (> +100º)

QRS voltage abnormalities: (Choose all that apply) ☐ **NONE**

- ☐ Low voltage
- ☐ Left ventricular hypertrophy
- ☐ Right ventricular hypertrophy

FORM NO. CNA024	
Acrostic Identifier:	
Study ID:	

Date source form completed: _____/_____/_____

ECG - *Baseline*

Intraventricular conduction abnormalities: (Choose all that apply) ☐ **NONE**

- ☐ Right bundle branch block, complete
- ☐ Right bundle branch block, incomplete
- ☐ Left anterior fascicular block
- ☐ Left posterior fascicular block
- ☐ Left bundle branch block, complete
- ☐ Left bundle branch block, incomplete
- ☐ Nonspecific intraventricular conduction disturbance

			For each "Yes" response, check all locations that apply:		
Are Q waves present?	Y ☐	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?	Y ☐	N ☐	Anterior ☐	Lateral ☐	Inferior ☐
Is there evidence of posterior infarction?	Y ☐	N ☐	Pathologic R wave V_2 ☐	Abn. ST depression V_1, V_2 ☐	Abn. ST elevation V_1, V_2 ☐
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 _____

FORM NO. CNA005	
Acrostic Identifier:	
Study ID:	
Date source form completed: _____/_____/_____	

Physical Exam - *Baseline*

Date of Exam: _____/_____/_____	☐ **Visit is outside time window**	**Reason:**

☐ **Informed consent was revised since study start date**

Date patient reconsented: ___/___/___ **Consent version:**

Vital Signs		**NYHA Class:**	**CCS Class:**
Height:	_____ inches	☐ I	☐ I
Weight:	_____ pounds	☐ II	☐ II
Temperature:	__ __.__°F ☐ oral ☐ auricle	☐ III	☐ III
Respirations:	__ __ breaths/minute	☐ IV	☐ IV
Heart rate:	__ __ __ beats/minute	☐ N/A	☐ N/A
Blood Pressure:	__ __ __ / __ __ __ mmHg (supine) SBP DBP	**LVEF: __ __ %** *(by Echo)*	Date: _____/_____/_____

Review of Systems:

Organs	Normal	Abnormal	Not Examined	Describe
Skin	☐	☐	☐	
HEENT	☐	☐	☐	
Lungs	☐	☐	☐	
CV	☐	☐	☐	
Abdomen	☐	☐	☐	
Lymph Nodes	☐	☐	☐	
Musculoskeletal	☐	☐	☐	
Neurological	☐	☐	☐	
Other: _____	☐	☐	☐	

Questions:

Has the patient experienced any adverse events since consent signed? (If yes, complete AE form)	Yes ☐ No ☐	
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 ☐
Was a chest x-ray completed? (If not done, or if result abnormal, please explain in comments)	Yes ☐ No ☐	Normal ☐ Abnormal ☐

FORM NO. CNA005			
Acrostic Identifier:			
Study ID:			
Date source form completed: _____/_____/_____			
Physical Exam - *Baseline*			
Questions:			
Was the baseline contrast Echo completed and results sent to the Core Lab? (If no, please enter a reason in Comments)	Yes ☐ No ☐		
Was the baseline SPECT Scanning completed and results sent to the Core Lab? (If no, please explain in Comments)	Yes ☐ No ☐		
Was the baseline Treadmill Test with MVO2 completed and results sent to the Core Lab? (If no, please explain in Comments)	Yes ☐ No ☐		Time of Test: _____:_____
If applicable, was an ICD interrogation completed? (If no, please explain in Comments)	Yes ☐ No ☐		N/A ☐
Has the patient completed Quality of Life Questionnaires? (If no, please explain in Comments)	Yes ☐ No ☐		
Has there been a change in nitrate usage since consent signed? (If yes, please update medication 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 completed: _____/_____/_____			
Laboratory Tests - *Baseline*			
Date and time specimen obtained: Date: ____/____/____ Time: __ __:__ __			
CBC with Differential	**Result**	**Unit**	**Normal Range**
WBC		K/mm^3	4.0-11.0 K/mm^3
RBC		M/mm^3	4.0-6.0 M/mm^3
Hgb		gm/dL	12.0-17.5 gm/dL
Hct		%	33-53%
MCV		fL	78-100 fL
Platelets		K/mm^3	135-450 K/mm^3
WBC Differential			
Neutrophilis		%	36-74%
Lymphocytes		%	12-45%
Monocytes		%	0-13%
Eosinophils		%	0-8%
Basophils		%	< 3.0%
Cardiac Markers (Either Troponin T or Troponin I should 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_2		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) ☐ 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/workbook completed: _____/_____/_____

Holter Data Form - *Baseline*

Date procedure started: _____/_____/_____

Total recording time: __ __:__ __

General:

Total beats/QRS Complexes: __ __ __ __ __ __ beats

Paced beats: __ __ __ __ __ __ beats

Pauses/Longest RR Interval (> 2 secs):

Longest pause was __ __ seconds @ __ __:__ __

Total number of pauses: __ __ __

Predominant Rhythm: *(mutually exclusive)*

☐ Sinus Rhythm ☐ Junctional Rhythm

☐ Paced Rhythm ☐ Ectopic Atrial Rhythm

☐ Atrial Flutter / Fibrillation

Heart Rates:

Minimum: __ __ __beats/min. @ __ __:__ __

Average: __ __ __beats/min.

Maximum: __ __ __beats/min. @ __ __:__ __

Ventricular Arrhythmia Summary:

Single/PVC: __ __ __ __ __ __ beats

Couplets: __ __ __ __ __ __

Total number of NSVT Runs (≥ 3 beats) __ __ __

Number of beats in longest NSVT run __ __ __

Total number of sustained ventricular tachycardia runs (≥ 30 secs) __ __ __

Supraventricular Arrhythmia Summary:

Single/PAC: __ __ __ __ __ __ beats

Couplets: __ __ __ __ __ __

Total number of SVT Runs __ __ __

Number of beats in longest SVT run __ __ __

Intermittent Atrial Fibrillation / Atrial Flutter:

☐ 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

__ __ __ total no. of episodes __ __ __ __ __ duration of longest episode (secs)

Comments:

PI Signature: _____ Date: _____

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? ☐ Yes ☐ No	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 _____

FORM NO.CNA061
Acrostic Identifier:
Study ID:
Date source form completed: _____/_____/_____

Minnesota Living With Heart Failure Questionnaire - *Baseline*

MINNESOTA LIVING WITH HEART FAILURE® QUESTIONNAIRE

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 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
2. making you sit or lie down to rest during the day?	0	1	2	3	4	5
3. making your walking about or climbing stairs difficult?	0	1	2	3	4	5
4. making your working around the house or yard difficult?	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 difficult?	0	1	2	3	4	5
7. making your relating to or doing things with your friends or family difficult?	0	1	2	3	4	5
8. making your working to earn a living difficult?	0	1	2	3	4	5
9. making your recreational pastimes, sports or hobbies difficult?	0	1	2	3	4	5
10. making your sexual activities difficult?	0	1	2	3	4	5
11. making you eat less of the foods you like?	0	1	2	3	4	5
12. making you short of breath?	0	1	2	3	4	5
13. making you tired, fatigued, or low on energy?	0	1	2	3	4	5
14. making you stay in a hospital?	0	1	2	3	4	5
15. costing you money for medical care?	0	1	2	3	4	5
16. giving you side effects from treatments?	0	1	2	3	4	5
17. making you feel you are a burden to your family or friends?	0	1	2	3	4	5
18. making you feel a loss of self-control in your life?	0	1	2	3	4	5
19. making you worry?	0	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?	0	1	2	3	4	5

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Comments:

Entered to eCRF ☐ Initials _____

FORM NO.CNA062
Acrostic Identifier:
Study ID:
Date form 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 ☒ in the one box that best describes your answer.

1. In general, would you say your health is:

Excellent	Very good	Good	Fair	Poor
☐1	☐2	☐3	☐4	☐5

2. <u>Compared to one year ago</u>, how would you rate your health in general <u>now</u>?

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.CNA062
Acrostic Identifier:
Study ID:
Date form completed: _____/_____/_____

SF-36 - *Baseline*

3. The following items are about activities you might do during a typical day. Does <u>your health now limit you</u> in these activities? If so, how much?

	Yes, limited a lot	Yes, limited a little	No, not limited at all
a <u>Vigorous activities</u>, such as running, lifting heavy objects, participating in strenuous sports	☐ 1	☐ 2	☐ 3
b <u>Moderate activities</u>, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	☐ 1	☐ 2	☐ 3
c Lifting or carrying groceries	☐ 1	☐ 2	☐ 3
d Climbing <u>several</u> flights of stairs	☐ 1	☐ 2	☐ 3
e Climbing <u>one</u> flight of stairs	☐ 1	☐ 2	☐ 3
f Bending, kneeling, or stooping	☐ 1	☐ 2	☐ 3
g Walking <u>more than a mile</u>	☐ 1	☐ 2	☐ 3
h Walking <u>several blocks</u>	☐ 1	☐ 2	☐ 3
i Walking <u>one block</u>	☐ 1	☐ 2	☐ 3
j Bathing or dressing yourself	☐ 1	☐ 2	☐ 3

FORM NO.CNA062
Acrostic Identifier:
Study ID:
Date form completed: _____/_____/_____

SF-36 - *Baseline*

4. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

	Yes	No
a Cut down on the amount of time you spent on work or other activities	☐ 1	☐ 2
b Accomplished less than you would like	☐ 1	☐ 2
c Were limited in the kind of work or other activities	☐ 1	☐ 2
d Had difficulty performing the work or other activities (for example, it took extra effort)	☐ 1	☐ 2

5. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

	Yes	No
a Cut down on the amount of time you spent on work or other activities	☐ 1	☐ 2
b Accomplished less than you would like	☐ 1	☐ 2
c Did work or other activities less carefully than usual	☐ 1	☐ 2

FORM NO.CNA062
Acrostic Identifier:
Study ID:
Date form completed: _____/_____/_____

SF-36 - *Baseline*

6. During the <u>past 4 weeks</u>, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?

Not at all	Slightly	Moderately	Quite a bit	Extremely
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

7. How much <u>bodily</u> pain have you had during the <u>past 4 weeks</u>?

None	Very mild	Mild	Moderate	Severe	Very Sever
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6

8. During the <u>past 4 weeks</u>, how much did <u>pain</u> interfere with your normal work (including both work outside the home and housework)?

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: _____/_____/_____

SF-36 - *Baseline*

9. These questions are about how you feel and how things have been with you during the <u>past 4 weeks</u>. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the <u>past 4 weeks</u>...

	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?	☐1	☐2	☐3	☐4	☐5	☐6
b Have you been a very nervous person?	☐1	☐2	☐3	☐4	☐5	☐6
c Have you felt so down in the dumps that nothing could cheer you up?	☐1	☐2	☐3	☐4	☐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	☐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

FORM NO.CNA062
Acrostic Identifier:
Study ID:
Date form completed: _____/_____/_____

SF-36 - *Baseline*

10. During the past 4 weeks, how much of the time has your physical health or emotional problems 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	☐ 2	☐ 3	☐ 4	☐ 5

11. How TRUE or FALSE is each of the following statements for you?

	Definitely true	Mostly true	Don't know	Mostly false	Definitely false
a. I seem to get sick a little easier than other people	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b. I am as healthy as anybody I know	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c. I expect my health to get worse	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
d. My health is excellent	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Comments:

Entered to eCRF ☐ Initials _____

FORM NO. CNA007

Acrostic Identifier:

Study ID:

Date form completed: _____/_____/_____

Treatment Checklist

The following variables are autopopulated from the previously completed Screen/Demographics, 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 ºF
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 (Troponin T)
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)
Creatinine		Must be ≤ 2.5 mg/dl

If any of the variables above have changed since the Baseline Physical Exam or Baseline Laboratory Tests and a more recent exam or test has been done, please enter the updated value, date, and time of 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). **Answers to questions 1 through 3 below cannot be overridden by this.**			
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 ☐	No ☐	
Comments:			

Entered to eCRF ☐ Initials _____

FORM NO. CNA005			
Acrostic Identifier:			
Study ID:			
Date source form completed: _____/_____/_____			
Physical Exam - *Day After Injection*			
Date of Exam: _____/_____/_____	☐ **Visit is outside time window**	**Reason:**	
☐ **Informed consent was revised since study start date** **Date patient reconsented:** ___/___/____ **Consent version:**			

Vital Signs		**NYHA Class:**	**CCS Class:**
Weight:	_____ pounds	☐ I	☐ I
Temperature:	_____°F ☐oral ☐auricle	☐ II	☐ II
Respirations:	__ __ breaths/minute	☐ III	☐ III
Heart rate:	__ __ __ beats/minute	☐ IV	☐ IV
Blood Pressure:	__ __ __ / __ __ __ mmHg (supine) SBP DBP	☐ N/A	☐ N/A

Review of Systems:

Have changes occurred since previous visit? Yes ☐ No ☐ If no, table is complete.

Organs	Normal	Abnormal	Not Examined	Describe
Skin	☐	☐	☐	
HEENT	☐	☐	☐	
Lungs	☐	☐	☐	
CV	☐	☐	☐	
Abdomen	☐	☐	☐	
Lymph Nodes	☐	☐	☐	
Musculoskeletal	☐	☐	☐	
Neurological	☐	☐	☐	
Other: _____	☐	☐	☐	

Questions

Has the patient experienced any new adverse events? (If yes, complete AE form)	Yes ☐ No ☐
Have there been any significant changes in physical findings since last visit? (If yes, please explain in comments)	Yes ☐ No ☐
Have there been any changes to medications? (If yes, update medication form)	Yes ☐ No ☐

FORM NO. CNA005			
Acrostic Identifier:			
Study ID:			
Date source form completed: _____/_____/_____			
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? (If no, please explain in the Comments) **Verify patient consented to Biorepository before you draw Biorepository bloods.**	Yes ☐ No ☐		
Has there been a change in nitrate usage since last visit? (If yes, please update medication 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 completed: _____/_____/_____			
Laboratory Tests - *Day After Injection*			
Date and time specimen obtained: **Date:** _____/_____/_____ **Time:** __ __:__ __			
CBC with Differential	**Result**	**Unit**	**Normal Range**
WBC		K/mm^3	4.0-11.0 K/mm^3
RBC		M/mm^3	4.0-6.0 M/mm^3
Hgb		gm/dL	12.0-17.5 gm/dL
Hct		%	33-53%
MCV		fL	78-100 fL
Platelets		K/mm^3	135-450 K/mm^3
WBC Differential			
Neutrophilis		%	36-74%
Lymphocytes		%	12-45%
Monocytes		%	0-13%
Eosinophils		%	0-8%
Basophils		%	< 3.0%
Cardiac Markers (Either Troponin T or Troponin I should be completed, NOT both)			
8 hour 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
16 hour 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
24 hour 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

FORM NO. CNA021			
Acrostic Identifier:			
Study ID:			
Date source form completed: _____/_____/_____			
Laboratory Tests - *Day 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 eCRF ☐ Initials _____

FORM NO. CNA024	
Acrostic Identifier:	
Study ID:	

Date source form completed: _____/_____/_____

ECG - *Day After Injection*

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
- ☐ sinus arrhythmia
- ☐ sinus bradycardia (<60 bpm)
- ☐ sinus tachycardia (>100 bpm)
- ☐ atrial fibrillation
- ☐ atrial flutter
- ☐ multifocal atrial tachycardia
- ☐ supraventricular tachycardia
- ☐ junctional tachycardia
- ☐ ventricular bigeminy
- ☐ ectopic atrial rhythm
- ☐ ventricular demand pacemaker (VVI)
- ☐ atrial pacemaker
- ☐ dual chamber pacemaker (DDD)
- ☐ wandering pacemaker
- ☐ accelerated idioventricular rhythm
- ☐ atrial premature complexes
- ☐ ventricular premature complexes (PVCs)
- ☐ ventricular couplets
- ☐ junctional rhythm
- ☐ ventricular fibrillation
- ☐ 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 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 enlargement

Abnormalities of QRS axis: (Choose one) ☐ **NONE**

- ☐ Left axis deviation(> -30º)
- ☐ Right axis deviation (> +100º)

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 - *Day After Injection*

Intraventricular conduction abnormalities: (Choose all that apply) ☐ **NONE**

- ☐ Right bundle branch block, complete
- ☐ Right bundle branch block, incomplete
- ☐ Left anterior fascicular block
- ☐ Left posterior fascicular block
- ☐ Left bundle branch block, complete
- ☐ Left bundle branch block, incomplete
- ☐ Nonspecific intraventricular conduction disturbance

			For each "Yes" response, check all locations that apply:		
Are Q waves present?	Y ☐	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?	Y ☐	N ☐	Anterior ☐	Lateral ☐	Inferior ☐
Is there evidence of posterior infarction?	Y ☐	N ☐	Pathologic wave V_2 ☐	R V_1, Abn. ST depression V_1, V_2 ☐	Abn. ST elevation V_1, V_2 ☐
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 _____

FORM NO. CNA070	
Acrostic Identifier:	
Study ID:	
Date source/workbook completed: _____/_____/_____	

Follow-Up Telephone Contact

Visit Type: ☐ Year 2 ☐ Year 3 ☐ Year 4 ☐ Year 5 ☐ Interim

Date of Call/Contact: _____/_____/_____

Contact Initiated by (check one): ☐ Site ☐ Subject

Questions being answered by: ☐ Patient ☐ Family Member ☐ Other

Section 1 - Vital Status

a. What is the patient's vital status? ☐ Living ☐ Deceased

If deceased, what is the known cause of death?	

b. Does the patient have an ICD? ☐ Yes ☐ No ☐ Unknown

If yes, estimate the date last fired:	
Estimate the number of ICD firings since the last study contact (in the last year):	

c. Is the patient on an assist device? ☐ Yes ☐ No ☐ Unknown

If yes,indicate device:	

d. Has the patient had a heart transplant? ☐ Yes ☐ No ☐ Unknown

If yes, indicate date:	

Section 2 - Hospitalizations and Diagnoses

Since the last time we spoke to you, have you had any hospitalizations for the following?

e. Heart attack (myocardial infarction) ☐ Yes ☐ No ☐ Unknown

If yes, provide estimated date:	

f. Bypass surgery (CABG) ☐ Yes ☐ No ☐ Unknown

If yes, provide estimated date:	

g. Other heart procedures (caths, stent, balloons, etc.) ☐ Yes ☐ No ☐ Unknown

1) Describe:	Date:
2) Describe:	Date:
3) Describe:	Date:

FORM NO. CNA070				
Acrostic Identifier:				
Study ID:				
Date source/workbook completed: _____/_____/_____				
Follow-Up Telephone Contact				
h. Resuscitative sudden death	☐ Yes	☐ No	☐ Unknown	
If yes, provide estimated date:				
i. Any cancer diagnoses (including skin)	☐ Yes	☐ No	☐ Unknown	
If yes, provide 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 History
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 Questionnaire
13. CNA062 SF-36
14. CNA007 Treatment Checklist

*CNA011 and CNA012 are on the same page

_____ _____

Signature Date

_____

Printed 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

_____ _____

Signature Date

_____

Printed 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

_____ _____

Signature Date

_____

Printed 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

_____ _____

Signature Date

_____

Printed 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

_____ _____

Signature Date

_____

Printed 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 Failure Questionnaire
6. CNA062 SF-36

_____ _____

Signature Date

_____

Printed 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 Questionnaire
7. CNA062 SF-36

_____ _____

Signature Date

_____

Printed 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 Tests
3. CNA024 ECG
4. CNA061 Minnesota Living with Heart Failure Questionnaire
5. CNA062 SF-36

_____ _____

Signature Date

_____

Printed 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

_____ _____

Signature Date

_____

Printed Name

FORM NO. CNA005	
Acrostic Identifier:	
Study ID:	
Date source form completed: _____/_____/_____	

Physical Exam - *Month 3*

Date of Exam: ____/____/____	☐ **Visit is outside time window**	**Reason:**

☐ **Informed consent was revised since study start date**

Date patient reconsented: ___/___/____ **Consent version:**

Vital Signs		**NYHA Class:**	**CCS Class:**
Weight:	_____ pounds	☐ I	☐ I
Temperature:	_____°F ☐oral ☐auricle	☐ II	☐ II
Respirations:	__ __ breaths/minute	☐ III	☐ III
Heart rate:	__ __ __ beats/minute	☐ IV	☐ IV
Blood Pressure:	__ __ __ / __ __ __ mmHg (supine) SBP DBP	☐ N/A	☐ N/A

Review of Systems:

Have changes occurred since previous visit? Yes☐ No ☐ If no, table is complete.

Organs	Normal	Abnormal	Not Examined	Describe
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)	Yes ☐ No ☐
Have there been any significant changes in physical findings since the last follow-up visit? (If yes, please explain in comments)	Yes ☐ No ☐
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 completed: _____/_____/_____			
Physical Exam - *Month 3*			
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 ☐	
Was a routine no contrast Echo completed? (If not done, or if result abnormal, please explain in comments)	Yes ☐ No ☐	Normal ☐ Abnormal ☐	
If applicable, was the ICD interrogation completed? (If no, please explain in Comments)	Yes ☐ No ☐	N/A ☐	
Has the patient completed the Quality of Life Questionnaires? (If no, please explain in Comments)	Yes ☐ No ☐		
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? (If no, please explain in the Comments) **Verify patient consented to Biorepository before you draw Biorepository bloods.**	Yes ☐ No ☐		
Has there been a change in nitrate usage since the last follow-up visit? (If yes, please update medication 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 completed: _____/_____/_____			
Laboratory Tests - *Month 3*			
Date and time specimen obtained: Date: ____/____/____ Time: __ __:__ __			
CBC with Differential	**Result**	**Unit**	**Normal Range**
WBC		K/mm^3	4.0-11.0 K/mm^3
RBC		M/mm^3	4.0-6.0 M/mm^3
Hgb		gm/dL	12.0-17.5 gm/dL
Hct		%	33-53%
MCV		fL	78-100 fL
Platelets		K/mm^3	135-450 K/mm^3
WBC Differential			
Neutrophilis		%	36-74%
Lymphocytes		%	12-45%
Monocytes		%	0-13%
Eosinophils		%	0-8%
Basophils		%	< 3.0%
Cardiac Markers (Either Troponin T or Troponin I should 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			
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

FORM NO. CNA021			
Acrostic Identifier:			
Study ID:			
Date source form completed: _____/_____/_____			
Laboratory Tests - *Month 3*			
Other Tests			
BNP		pg/ml	0-100 pg/ml
hsCRP		mg/L	0.0-40 mg/L
Pregnancy Test (women of 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 Form - *Month 3*

Date procedure started: _____/_____/_____

Total recording time: __ __:__ __

General:

Total beats/QRS Complexes: __ __ __ __ __ __ beats

Paced beats: __ __ __ __ __ __ beats

Pauses/Longest RR Interval (> 2 secs):

Longest pause was __ __ seconds @ __ __:__ __

Total number of pauses: __ __ __

Predominant Rhythm: *(mutually exclusive)*

☐ Sinus Rhythm ☐ Junctional Rhythm

☐ Paced Rhythm ☐ Ectopic Atrial Rhythm

☐ Atrial Flutter / Fibrillation

Heart Rates:

Minimum: __ __ __beats/min. @ __ __:__ __

Average: __ __ __beats/min.

Maximum: __ __ __beats/min. @ __ __:__ __

Ventricular Arrhythmia Summary:

Single/PVC: __ __ __ __ __ __ beats

Couplets: __ __ __ __ __ __

Total number of NSVT Runs (≥ 3 beats) __ __ __

Number of beats in longest NSVT run __ __ __

Total number of sustained ventricular tachycardia runs (≥ 30 secs) __ __ __

Supraventricular Arrhythmia Summary:

Single/PAC: __ __ __ __ __ __ beats

Couplets: __ __ __ __ __ __

Total number of SVT Runs __ __ __

Number of beats in longest SVT run __ __ __

Intermittent Atrial Fibrillation / Atrial Flutter:

☐ 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

__ __ __ total no. of episodes __ __ __ __ __ duration 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
- ☐ sinus arrhythmia
- ☐ sinus bradycardia (<60 bpm)
- ☐ sinus tachycardia (>100 bpm)
- ☐ atrial fibrillation
- ☐ atrial flutter
- ☐ multifocal atrial tachycardia
- ☐ supraventricular tachycardia
- ☐ junctional tachycardia
- ☐ ventricular bigeminy
- ☐ ectopic atrial rhythm
- ☐ ventricular demand pacemaker (VVI)
- ☐ atrial pacemaker
- ☐ dual chamber pacemaker (DDD)
- ☐ wandering pacemaker
- ☐ accelerated idioventricular rhythm
- ☐ atrial premature complexes
- ☐ ventricular premature complexes (PVCs)
- ☐ ventricular couplets
- ☐ junctional rhythm
- ☐ ventricular fibrillation
- ☐ 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 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 enlargement

Abnormalities of QRS axis: (Choose one) ☐ **NONE**

- ☐ Left axis deviation(> -30º)
- ☐ Right axis deviation (> +100º)

QRS voltage abnormalities: (Choose all that apply) ☐ **NONE**

- ☐ Low voltage
- ☐ Left ventricular hypertrophy
- ☐ Right ventricular hypertrophy

FORM NO. CNA024	
Acrostic Identifier:	
Study ID:	

Date source form completed: _____/_____/_____

ECG - *Month 3*

Intraventricular conduction abnormalities: (Choose all that apply) ☐ **NONE**

- ☐ Right bundle branch block, complete
- ☐ Right bundle branch block, incomplete
- ☐ Left anterior fascicular block
- ☐ Left posterior fascicular block
- ☐ Left bundle branch block, complete
- ☐ Left bundle branch block, incomplete
- ☐ Nonspecific intraventricular conduction disturbance

			For each "Yes" response, check all locations that apply:		
Are Q waves present?	Y ☐	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?	Y ☐	N ☐	Anterior ☐	Lateral ☐	Inferior ☐
Is there evidence of posterior infarction?	Y ☐	N ☐	Pathologic wave V_2 ☐	R V_1, Abn. ST depression V_1, V_2 ☐	Abn. ST elevation V_1, V_2 ☐
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 _____

FORM NO.CNA061
Acrostic Identifier:
Study ID:
Date source form completed: _____/_____/_____

Minnesota Living With Heart Failure Questionnaire - *Month 3*

MINNESOTA LIVING WITH HEART FAILURE® QUESTIONNAIRE

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 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
2. making you sit or lie down to rest during the day?	0	1	2	3	4	5
3. making your walking about or climbing stairs difficult?	0	1	2	3	4	5
4. making your working around the house or yard difficult?	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 difficult?	0	1	2	3	4	5
7. making your relating to or doing things with your friends or family difficult?	0	1	2	3	4	5
8. making your working to earn a living difficult?	0	1	2	3	4	5
9. making your recreational pastimes, sports or hobbies difficult?	0	1	2	3	4	5
10. making your sexual activities difficult?	0	1	2	3	4	5
11. making you eat less of the foods you like?	0	1	2	3	4	5
12. making you short of breath?	0	1	2	3	4	5
13. making you tired, fatigued, or low on energy?	0	1	2	3	4	5
14. making you stay in a hospital?	0	1	2	3	4	5
15. costing you money for medical care?	0	1	2	3	4	5
16. giving you side effects from treatments?	0	1	2	3	4	5
17. making you feel you are a burden to your family or friends?	0	1	2	3	4	5
18. making you feel a loss of self-control in your life?	0	1	2	3	4	5
19. making you worry?	0	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?	0	1	2	3	4	5

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Comments:

Entered to eCRF ☐ Initials _____

FORM NO.CNA062
Acrostic Identifier:
Study ID:
Date form completed: _____/_____/_____

SF-36 - *Month 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. *Thank you for completing this survey!*

For each of the following questions, please mark an ☒ in the one box that best describes your answer.

1. In general, would you say your health is:

Excellent	Very good	Good	Fair	Poor
☐1	☐2	☐3	☐4	☐5

2. <u>Compared to one year ago</u>, how would you rate your health in general <u>now</u>?

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.CNA062
Acrostic Identifier:
Study ID:
Date form completed: _____/_____/_____
SF-36 - *Month 3*

3. The following items are about activities you might do during a typical day. Does <u>your health now limit you</u> in these activities? If so, how much?

	Yes, limited a lot	Yes, limited a little	No, not limited at all
a <u>Vigorous activities</u>, such as running, lifting heavy objects, participating in strenuous sports	☐ 1	☐ 2	☐ 3
b <u>Moderate activities</u>, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	☐ 1	☐ 2	☐ 3
c Lifting or carrying groceries	☐ 1	☐ 2	☐ 3
d Climbing <u>several</u> flights of stairs	☐ 1	☐ 2	☐ 3
e Climbing <u>one</u> flight of stairs	☐ 1	☐ 2	☐ 3
f Bending, kneeling, or stooping	☐ 1	☐ 2	☐ 3
g Walking <u>more than a mile</u>	☐ 1	☐ 2	☐ 3
h Walking <u>several blocks</u>	☐ 1	☐ 2	☐ 3
i Walking <u>one block</u>	☐ 1	☐ 2	☐ 3
j Bathing or dressing yourself	☐ 1	☐ 2	☐ 3

FORM NO.CNA062
Acrostic Identifier:
Study ID:
Date form completed: _____/_____/_____

SF-36 - *Month 3*

4. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

	Yes	No
a Cut down on the amount of time you spent on work or other activities	☐ 1	☐ 2
b Accomplished less than you would like	☐ 1	☐ 2
c Were limited in the kind of work or other activities	☐ 1	☐ 2
d Had difficulty performing the work or other activities (for example, it took extra effort)	☐ 1	☐ 2

5. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

	Yes	No
a Cut down on the amount of time you spent on work or other activities	☐ 1	☐ 2
b Accomplished less than you would like	☐ 1	☐ 2
c Did work or other activities less carefully than usual	☐ 1	☐ 2

FORM NO.CNA062
Acrostic Identifier:
Study ID:
Date form completed: _____/_____/_____

SF-36 - *Month 3*

6. During the <u>past 4 weeks</u>, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?

Not at all	Slightly	Moderately	Quite a bit	Extremely
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

7. How much <u>bodily</u> pain have you had during the <u>past 4 weeks</u>?

None	Very mild	Mild	Moderate	Severe	Very Sever
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6

8. During the <u>past 4 weeks</u>, how much did <u>pain</u> interfere with your normal work (including both work outside the home and housework)?

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: _____/_____/_____

SF-36 - *Month 3*

9. These questions are about how you feel and how things have been with you during the <u>past 4 weeks</u>. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the <u>past 4 weeks</u>...

	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?	☐1	☐2	☐3	☐4	☐5	☐6
b Have you been a very nervous person?	☐1	☐2	☐3	☐4	☐5	☐6
c Have you felt so down in the dumps that nothing could cheer you up?	☐1	☐2	☐3	☐4	☐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	☐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

FORM NO.CNA062
Acrostic Identifier:
Study ID:
Date form completed: _____/_____/_____

SF-36 - *Month 3*

10. During the past 4 weeks, how much of the time has your physical health or emotional problems 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	☐ 2	☐ 3	☐ 4	☐ 5

11. How TRUE or FALSE is each of the following statements for you?

	Definitely true	Mostly true	Don't know	Mostly false	Definitely false
a. I seem to get sick a little easier than other people	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b. I am as healthy as anybody I know	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c. I expect my health to get worse	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
d. My health is excellent	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Comments:

Entered to eCRF ☐ Initials _____

FORM NO. CNA005	
Acrostic Identifier:	
Study ID:	
Date source form completed: _____/_____/_____	

Physical Exam - *Month 6*

Date of Exam: ____/____/____	☐ **Visit is outside time window**	**Reason:**

☐ **Informed consent was revised since study start date**

Date patient reconsented: ___/____/____ **Consent version:**

Vital Signs		**NYHA Class:**	**CCS Class:**
Weight:	_____ pounds	☐ I	☐ I
Temperature:	_____°F ☐oral ☐auricle	☐ II	☐ II
Respirations:	__ __ breaths/minute	☐ III	☐ III
Heart rate:	__ __ __ beats/minute	☐ IV	☐ IV
Blood Pressure:	__ __ __ / __ __ __ mmHg (supine) SBP DBP	☐ N/A	☐ N/A

Review of Systems:

Have changes occurred since previous visit? Yes☐ No☐ If no, table is complete.

Organs	Normal	Abnormal	Not Examined	Describe
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)	Yes ☐ No ☐
Have there been any significant changes in physical findings since the last follow-up visit? (If yes, please explain in comments)	Yes ☐ No ☐
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 completed: _____/_____/_____	

Physical Exam - *Month 6*

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 ☐
Was the MRI (if applicable) completed and results sent to the Core Lab? (If no, please explain in Comments)	Yes ☐ No ☐	N/A ☐
Was the chest x-ray completed? (If not done, or if result abnormal, please explain in comments)	Yes ☐ No ☐	Normal ☐ Abnormal ☐
Was the contrast Echo completed and results sent to the Core Lab? (If no, please enter a reason in Comments)	Yes ☐ No ☐	
Was the SPECT Scanning completed and results sent to the Core Lab? (If no, please explain in Comments)	Yes ☐ No ☐	
Was the Treadmill Test with MVO2 completed and results sent to the Core Lab? (If no, please explain in Comments)	Yes ☐ No ☐	Time of Test: ___:___
If applicable, was the ICD interrogation completed? (If no, please explain in Comments)	Yes ☐ No ☐	N/A ☐
Has the patient completed the Quality of Life Questionnaires? (If no, please explain in Comments)	Yes ☐ No ☐	
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? (If no, please explain in the Comments) **Verify patient consented to Biorepository before you draw Biorepository bloods.**	Yes ☐ No ☐	
Has there been a change in nitrate usage since the last follow-up visit? (If yes, please update medication 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 completed: _____/_____/_____			
Laboratory Tests - *Month 6*			
Date and time specimen obtained: Date: ____/____/____ Time: __ __:__ __			
CBC with Differential	**Result**	**Unit**	**Normal Range**
WBC		K/mm^3	4.0-11.0 K/mm^3
RBC		M/mm^3	4.0-6.0 M/mm^3
Hgb		gm/dL	12.0-17.5 gm/dL
Hct		%	33-53%
MCV		fL	78-100 fL
Platelets		K/mm^3	135-450 K/mm^3
WBC Differential			
Neutrophilis		%	36-74%
Lymphocytes		%	12-45%
Monocytes		%	0-13%
Eosinophils		%	0-8%
Basophils		%	< 3.0%
Cardiac Markers (Either Troponin T or Troponin I should 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			
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

FORM NO. CNA021			
Acrostic Identifier:			
Study ID:			
Date source form completed: _____/_____/_____			
Laboratory Tests - *Month 6*			
Other Tests			
BNP		pg/ml	0-100 pg/ml
hsCRP		mg/L	0.0-40 mg/L
Pregnancy Test (women of childbearing potential) ☐ Not applicable			Negative (urine) < 5.0 mU/ml (quantitative blood)
Comments:			

PI Signature _____ Date: _____

Entered to eCRF ☐ Initials _____

FORM NO. CNA027	
Acrostic Identifier:	
Study ID:	
Date source form completed: _____/_____/_____	
Six Minute 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? ☐ Yes ☐ No	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 _____

FORM NO. CNA023

Acrostic Identifier:	
Study ID:	
Date source/workbook completed: _____/_____/_____	

Holter Data Form - *Month 6*

Date procedure started: _____/_____/_____

Total recording time: __ __:__ __

General:

Total beats/QRS Complexes: __ __ __ __ __ __ beats

Paced beats: __ __ __ __ __ __ beats

Pauses/Longest RR Interval (> 2 secs):

Longest pause was __ __ seconds @ __ __:__ __

Total number of pauses: __ __ __

Predominant Rhythm: *(mutually exclusive)*

☐ Sinus Rhythm ☐ Junctional Rhythm

☐ Paced Rhythm ☐ Ectopic Atrial Rhythm

☐ Atrial Flutter / Fibrillation

Heart Rates:

Minimum: __ __ __beats/min. @ __ __:__ __

Average: __ __ __beats/min.

Maximum: __ __ __beats/min. @ __ __:__ __

Ventricular Arrhythmia Summary:

Single/PVC: __ __ __ __ __ __ beats

Couplets: __ __ __ __ __ __

Total number of NSVT Runs (≥ 3 beats) __ __ __

Number of beats in longest NSVT run __ __ __

Total number of sustained ventricular tachycardia runs (≥ 30 secs) __ __ __

Supraventricular Arrhythmia Summary:

Single/PAC: __ __ __ __ __ __ beats

Couplets: __ __ __ __ __ __

Total number of SVT Runs __ __ __

Number of beats in longest SVT run __ __ __

Intermittent Atrial Fibrillation / Atrial Flutter:

☐ 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

__ __ __ total no. of episodes __ __ __ __ __ duration 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 6*

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
- ☐ sinus arrhythmia
- ☐ sinus bradycardia (<60 bpm)
- ☐ sinus tachycardia (>100 bpm)
- ☐ atrial fibrillation
- ☐ atrial flutter
- ☐ multifocal atrial tachycardia
- ☐ supraventricular tachycardia
- ☐ junctional tachycardia
- ☐ ventricular bigeminy
- ☐ ectopic atrial rhythm
- ☐ ventricular demand pacemaker (VVI)
- ☐ atrial pacemaker
- ☐ dual chamber pacemaker (DDD)
- ☐ wandering pacemaker
- ☐ accelerated idioventricular rhythm
- ☐ atrial premature complexes
- ☐ ventricular premature complexes (PVCs)
- ☐ ventricular couplets
- ☐ junctional rhythm
- ☐ ventricular fibrillation
- ☐ 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 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 enlargement

Abnormalities of QRS axis: (Choose one) ☐ **NONE**

- ☐ Left axis deviation(> -30º)
- ☐ Right axis deviation (> +100º)

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 - *Month 6*

Intraventricular conduction abnormalities: (Choose all that apply) ☐ **NONE**

- ☐ Right bundle branch block, complete
- ☐ Right bundle branch block, incomplete
- ☐ Left anterior fascicular block
- ☐ Left posterior fascicular block
- ☐ Left bundle branch block, complete
- ☐ Left bundle branch block, incomplete
- ☐ Nonspecific intraventricular conduction disturbance

			For each "Yes" response, check all locations that apply:		
Are Q waves present?	Y ☐	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?	Y ☐	N ☐	Anterior ☐	Lateral ☐	Inferior ☐
Is there evidence of posterior infarction?	Y ☐	N ☐	Pathologic wave V_2 ☐	R V_1, Abn. ST depression V_1, V_2 ☐	Abn. ST elevation V_1, V_2 ☐
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 _____

FORM NO.CNA061
Acrostic Identifier:
Study ID:
Date source form completed: _____/_____/_____

Minnesota Living With Heart Failure Questionnaire - *Month 6*

MINNESOTA LIVING WITH HEART FAILURE® QUESTIONNAIRE

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 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
2. making you sit or lie down to rest during the day?	0	1	2	3	4	5
3. making your walking about or climbing stairs difficult?	0	1	2	3	4	5
4. making your working around the house or yard difficult?	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 difficult?	0	1	2	3	4	5
7. making your relating to or doing things with your friends or family difficult?	0	1	2	3	4	5
8. making your working to earn a living difficult?	0	1	2	3	4	5
9. making your recreational pastimes, sports or hobbies difficult?	0	1	2	3	4	5
10. making your sexual activities difficult?	0	1	2	3	4	5
11. making you eat less of the foods you like?	0	1	2	3	4	5
12. making you short of breath?	0	1	2	3	4	5
13. making you tired, fatigued, or low on energy?	0	1	2	3	4	5
14. making you stay in a hospital?	0	1	2	3	4	5
15. costing you money for medical care?	0	1	2	3	4	5
16. giving you side effects from treatments?	0	1	2	3	4	5
17. making you feel you are a burden to your family or friends?	0	1	2	3	4	5
18. making you feel a loss of self-control in your life?	0	1	2	3	4	5
19. making you worry?	0	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?	0	1	2	3	4	5

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Comments:

Entered to eCRF ☐ Initials _____

FORM NO.CNA062
Acrostic Identifier:
Study ID:
Date form completed: _____/_____/_____

SF-36 - *Month 6*

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 ☒ in the one box that best describes your answer.

1. In general, would you say your health is:

Excellent	Very good	Good	Fair	Poor
☐1	☐2	☐3	☐4	☐5

2. <u>Compared to one year ago</u>, how would you rate your health in general <u>now</u>?

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.CNA062
Acrostic Identifier:
Study ID:
Date form completed: _____/_____/_____
SF-36 - *Month 6*

3. The following items are about activities you might do during a typical day. Does <u>your health now limit you</u> in these activities? If so, how much?

	Yes, limited a lot	Yes, limited a little	No, not limited at all
a <u>Vigorous activities</u>, such as running, lifting heavy objects, participating in strenuous sports	☐1	☐2	☐3
b <u>Moderate activities</u>, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	☐1	☐2	☐3
c Lifting or carrying groceries	☐1	☐2	☐3
d Climbing <u>several</u> flights of stairs	☐1	☐2	☐3
e Climbing <u>one</u> flight of stairs	☐1	☐2	☐3
f Bending, kneeling, or stooping	☐1	☐2	☐3
g Walking <u>more than a mile</u>	☐1	☐2	☐3
h Walking <u>several blocks</u>	☐1	☐2	☐3
i Walking <u>one block</u>	☐1	☐2	☐3
j Bathing or dressing yourself	☐1	☐2	☐3

FORM NO.CNA062
Acrostic Identifier:
Study ID:
Date form completed: _____/_____/_____

SF-36 - *Month 6*

4. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

	Yes	No
a Cut down on the amount of time you spent on work or other activities	☐ 1	☐ 2
b Accomplished less than you would like	☐ 1	☐ 2
c Were limited in the kind of work or other activities	☐ 1	☐ 2
d Had difficulty performing the work or other activities (for example, it took extra effort)	☐ 1	☐ 2

5. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

	Yes	No
a Cut down on the amount of time you spent on work or other activities	☐ 1	☐ 2
b Accomplished less than you would like	☐ 1	☐ 2
c Did work or other activities less carefully than usual	☐ 1	☐ 2

FORM NO.CNA062
Acrostic Identifier:
Study ID:
Date form completed: _____/_____/_____

SF-36 - *Month 6*

6. During the <u>past 4 weeks</u>, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?

Not at all	Slightly	Moderately	Quite a bit	Extremely
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

7. How much <u>bodily</u> pain have you had during the <u>past 4 weeks</u>?

None	Very mild	Mild	Moderate	Severe	Very Sever
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6

8. During the <u>past 4 weeks</u>, how much did <u>pain</u> interfere with your normal work (including both work outside the home and housework)?

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: _____/_____/_____

SF-36 - *Month 6*

9. These questions are about how you feel and how things have been with you during the <u>past 4 weeks</u>. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the <u>past 4 weeks</u>...

	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?	☐1	☐2	☐3	☐4	☐5	☐6
b Have you been a very nervous person?	☐1	☐2	☐3	☐4	☐5	☐6
c Have you felt so down in the dumps that nothing could cheer you up?	☐1	☐2	☐3	☐4	☐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	☐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

FORM NO.CNA062
Acrostic Identifier:
Study ID:
Date form completed: _____/_____/_____

SF-36 - *Month 6*

10. During the past 4 weeks, how much of the time has your physical health or emotional problems 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	☐ 2	☐ 3	☐ 4	☐ 5

11. How TRUE or FALSE is each of the following statements for you?

	Definitely true	Mostly true	Don't know	Mostly false	Definitely false
a. I seem to get sick a little easier than other people	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b. I am as healthy as anybody I know	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c. I expect my health to get worse	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
d. My health is excellent	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Comments:

Entered to eCRF ☐ Initials _____

FORM NO. CNA005	
Acrostic Identifier:	
Study ID:	
Date source form completed: _____/_____/_____	

Physical Exam - *Month 12*

Date of Exam: ____/____/____	☐ **Visit is outside time window**	**Reason:**

☐ **Informed consent was revised since study start date**

Date patient reconsented: ___/___/____ **Consent version:**

Vital Signs		**NYHA Class:**	**CCS Class:**
Weight:	_____ pounds	☐ I	☐ I
Temperature:	_____°F ☐oral ☐auricle	☐ II	☐ II
Respirations:	__ __ breaths/minute	☐ III	☐ III
Heart rate:	__ __ __ beats/minute	☐ IV	☐ IV
Blood Pressure:	__ __ __ / __ __ __ mmHg (supine) SBP DBP	☐ N/A	☐ N/A

Review of Systems:

Have changes occurred since previous visit? Yes ☐ No ☐ If no, table is complete.

Organs	Normal	Abnormal	Not Examined	Describe
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)	Yes ☐ No ☐
Have there been any significant changes in physical findings since the last follow-up visit? (If yes, please explain in comments)	Yes ☐ No ☐
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 completed: _____/_____/_____			
Physical Exam - *Month 12*			
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 ☐	
Has the patient completed the Quality of Life Questionnaires? (If no, please explain in Comments)	Yes ☐ No ☐		
Has there been a change in nitrate usage since the last follow-up visit? (If yes, please update medication form)	Yes ☐ No ☐	N/A ☐	
***Please remember to update 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 **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
- ☐ sinus arrhythmia
- ☐ sinus bradycardia (<60 bpm)
- ☐ sinus tachycardia (>100 bpm)
- ☐ atrial fibrillation
- ☐ atrial flutter
- ☐ multifocal atrial tachycardia
- ☐ supraventricular tachycardia
- ☐ junctional tachycardia
- ☐ ventricular bigeminy
- ☐ ectopic atrial rhythm
- ☐ ventricular demand pacemaker (VVI)
- ☐ atrial pacemaker
- ☐ dual chamber pacemaker (DDD)
- ☐ wandering pacemaker
- ☐ accelerated idioventricular rhythm
- ☐ atrial premature complexes
- ☐ ventricular premature complexes (PVCs)
- ☐ ventricular couplets
- ☐ junctional rhythm
- ☐ ventricular fibrillation
- ☐ 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 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 enlargement

Abnormalities of QRS axis: (Choose one) ☐ **NONE**

- ☐ Left axis deviation(> -30º)
- ☐ Right axis deviation (> +100º)

QRS voltage abnormalities: (Choose all that apply) ☐ **NONE**

- ☐ Low voltage
- ☐ Left ventricular hypertrophy
- ☐ Right ventricular hypertrophy

FORM NO. CNA024	
Acrostic Identifier:	
Study ID:	

Date source form completed: _____/_____/_____

ECG - *Month 12*

Intraventricular conduction abnormalities: (Choose all that apply) ☐ **NONE**

- ☐ Right bundle branch block, complete
- ☐ Right bundle branch block, incomplete
- ☐ Left anterior fascicular block
- ☐ Left posterior fascicular block
- ☐ Left bundle branch block, complete
- ☐ Left bundle branch block, incomplete
- ☐ Nonspecific intraventricular conduction disturbance

			For each "Yes" response, check all locations that apply:		
Are Q waves present?	Y ☐	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?	Y ☐	N ☐	Anterior ☐	Lateral ☐	Inferior ☐
Is there evidence of posterior infarction?	Y ☐	N ☐	Pathologic wave V_2 ☐	R V_1, Abn. ST depression V_1, V_2 ☐	Abn. ST elevation V_1, V_2 ☐
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 _____

FORM NO. CNA022			
Acrostic Identifier:			
Study ID:			
Date source form completed: _____/_____/_____			
Laboratory Tests - *Month 12*			
Date and time specimen obtained: Date: ____/____/____ Time: __ __:__ __			
Test	**Result**	**Unit**	**Normal Range**
BNP		pg/ml	0-100 pg/ml
Pregnancy Test (women of childbearing potential) ☐ Not applicable			Negative (urine) < 5.0 mU/ml (quantitative blood)
Comments:			

PI Signature _____ Date: _____

Entered to eCRF ☐ Initials _____

FORM NO.CNA061
Acrostic Identifier:
Study ID:
Date source form completed: _____/_____/_____

Minnesota Living With Heart Failure Questionnaire - *Month 12*

MINNESOTA LIVING WITH HEART FAILURE® QUESTIONNAIRE

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 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
2. making you sit or lie down to rest during the day?	0	1	2	3	4	5
3. making your walking about or climbing stairs difficult?	0	1	2	3	4	5
4. making your working around the house or yard difficult?	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 difficult?	0	1	2	3	4	5
7. making your relating to or doing things with your friends or family difficult?	0	1	2	3	4	5
8. making your working to earn a living difficult?	0	1	2	3	4	5
9. making your recreational pastimes, sports or hobbies difficult?	0	1	2	3	4	5
10. making your sexual activities difficult?	0	1	2	3	4	5
11. making you eat less of the foods you like?	0	1	2	3	4	5
12. making you short of breath?	0	1	2	3	4	5
13. making you tired, fatigued, or low on energy?	0	1	2	3	4	5
14. making you stay in a hospital?	0	1	2	3	4	5
15. costing you money for medical care?	0	1	2	3	4	5
16. giving you side effects from treatments?	0	1	2	3	4	5
17. making you feel you are a burden to your family or friends?	0	1	2	3	4	5
18. making you feel a loss of self-control in your life?	0	1	2	3	4	5
19. making you worry?	0	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?	0	1	2	3	4	5

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Comments:

Entered to eCRF ☐ Initials _____

FORM NO.CNA062
Acrostic Identifier:
Study ID:
Date 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. *Thank you for completing this survey!*

For each of the following questions, please mark an ☒ in the one box that best describes your answer.

1. In general, would you say your health is:

Excellent	Very good	Good	Fair	Poor
☐1	☐2	☐3	☐4	☐5

2. <u>Compared to one year ago</u>, how would you rate your health in general <u>now</u>?

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.CNA062
Acrostic Identifier:
Study ID:
Date form completed: _____/_____/_____
SF-36 - *Month 12*

3. The following items are about activities you might do during a typical day. Does <u>your health now limit you</u> in these activities? If so, how much?

	Yes, limited a lot	Yes, limited a little	No, not limited at all
a <u>Vigorous activities</u>, such as running, lifting heavy objects, participating in strenuous sports	☐1	☐2	☐3
b <u>Moderate activities</u>, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	☐1	☐2	☐3
c Lifting or carrying groceries	☐1	☐2	☐3
d Climbing <u>several</u> flights of stairs	☐1	☐2	☐3
e Climbing <u>one</u> flight of stairs	☐1	☐2	☐3
f Bending, kneeling, or stooping	☐1	☐2	☐3
g Walking <u>more than a mile</u>	☐1	☐2	☐3
h Walking <u>several blocks</u>	☐1	☐2	☐3
i Walking <u>one block</u>	☐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 past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

	Yes	No
a Cut down on the amount of time you spent on work or other activities	☐ 1	☐ 2
b Accomplished less than you would like	☐ 1	☐ 2
c Were limited in the kind of work or other activities	☐ 1	☐ 2
d Had difficulty performing the work or other activities (for example, it took extra effort)	☐ 1	☐ 2

5. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

	Yes	No
a Cut down on the amount of time you spent on work or other activities	☐ 1	☐ 2
b Accomplished less than you would like	☐ 1	☐ 2
c Did work or other activities less carefully than usual	☐ 1	☐ 2

FORM NO.CNA062
Acrostic Identifier:
Study ID:
Date form completed: _____/_____/_____

SF-36 - *Month 12*

6. During the <u>past 4 weeks</u>, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?

Not at all	Slightly	Moderately	Quite a bit	Extremely
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

7. How much <u>bodily</u> pain have you had during the <u>past 4 weeks</u>?

None	Very mild	Mild	Moderate	Severe	Very Sever
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6

8. During the <u>past 4 weeks</u>, how much did <u>pain</u> interfere with your normal work (including both work outside the home and housework)?

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: _____/_____/_____

SF-36 - *Month 12*

9. These questions are about how you feel and how things have been with you during the <u>past 4 weeks</u>. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the <u>past 4 weeks</u>...

	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?	☐1	☐2	☐3	☐4	☐5	☐6
b Have you been a very nervous person?	☐1	☐2	☐3	☐4	☐5	☐6
c Have you felt so down in the dumps that nothing could cheer you up?	☐1	☐2	☐3	☐4	☐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	☐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

FORM NO.CNA062
Acrostic Identifier:
Study ID:
Date form completed: _____/_____/_____

SF-36 - *Month 12*

10. During the past 4 weeks, how much of the time has your physical health or emotional problems 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	☐ 2	☐ 3	☐ 4	☐ 5

11. How TRUE or FALSE is each of the following statements for you?

	Definitely true	Mostly true	Don't know	Mostly false	Definitely false
a. I seem to get sick a little easier than other people	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b. I am as healthy as anybody I know	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c. I expect my health to get worse	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
d. My health is excellent	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Comments:

Entered to eCRF ☐ Initials _____

FORM NO. CNA005			
Acrostic Identifier:			
Study ID:			
Date source form completed: _____/_____/_____			
Physical Exam - *Interim*			
Date of Exam: ____/____/____	☐ **Visit is outside time window**	**Reason:**	
☐ **Informed consent was revised since study start date** **Date patient reconsented:** ___/___/____ **Consent version:**			

Vital Signs		**NYHA Class:**	**CCS Class:**
Weight:	_____ pounds	☐ I	☐ I
Temperature:	_____°F ☐oral ☐auricle	☐ II	☐ II
Respirations:	__ __ breaths/minute	☐ III	☐ III
Heart rate:	__ __ __ beats/minute	☐ IV	☐ IV
Blood Pressure:	__ __ __ / __ __ __ mmHg (supine) SBP DBP	☐ N/A	☐ N/A
		LVEF: __ __ **%** *(by Echo)*	Date: _____/_____/_____

Review of Systems:

Have changes occurred since previous visit? Yes☐ No☐ If no, table is complete.

Organs	Normal	Abnormal	Not Examined	Describe
Skin	☐	☐	☐	
HEENT	☐	☐	☐	
Lungs	☐	☐	☐	
CV	☐	☐	☐	
Abdomen	☐	☐	☐	
Lymph Nodes	☐	☐	☐	
Musculoskeletal	☐	☐	☐	
Neurological	☐	☐	☐	
Other: _____	☐	☐	☐	

FORM NO. CNA005			
Acrostic Identifier:			
Study ID:			
Date source form completed: _____/_____/_____			
Physical Exam - *Interim*			
Questions			
Has the patient experienced a new adverse event since the last follow-up visit? (If yes, complete AE form)	Yes ☐	No ☐	
Have there been any significant changes in physical findings since the last follow-up visit? (If yes, please explain in comments)	Yes ☐	No ☐	
Have there been any changes to medications since the last follow-up visit? (If yes, update medication form)	Yes ☐	No ☐	
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 ☐
Has there been a change in nitrate usage since the last follow-up visit? (If yes, please update medication form)	Yes ☐	No ☐	N/A ☐
***Please remember to update medication form with inter-visit changes to medications**			
Comments:			

Entered to eCRF ☐ Initials _____

FORM NO. CNA026			
Acrostic Identifier:			
Study ID:			
Date source form completed: _____/_____/_____			
Laboratory Tests - *Interim*			
Date and time specimen obtained: Date: ____/____/____ Time: __ __:__ __			
CBC with Differential	**Result**	**Unit**	**Normal Range**
WBC		K/mm^3	4.0-11.0 K/mm^3
RBC		M/mm^3	4.0-6.0 M/mm^3
Hgb		gm/dL	12.0-17.5 gm/dL
Hct		%	33-53%
MCV		fL	78-100 fL
Platelets		K/mm^3	135-450 K/mm^3
WBC Differential			
Neutrophilis		%	36-74%
Lymphocytes		%	12-45%
Monocytes		%	0-13%
Eosinophils		%	0-8%
Basophils		%	< 3.0%
Cardiac Markers (Either Troponin T or Troponin I should 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_2		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 completed: _____/_____/_____			
Laboratory Tests - *Interim*			
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) ☐ Not applicable			Negative (urine) < 5.0 mU/ml (quantitative blood)
Comments:			

PI Signature _____ Date: _____

Entered to eCRF ☐ Initials _____

FORM NO. CNA041

Acrostic Identifier:

Study ID:

Adverse Event Log

Date of this Report: _____/_____/_____

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	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 include the following: detailed description of event, problem, and/or product use error, and relevant tests/laboratory data, including dates

PI Signature_____ Date:_____

RNC Signature_____ Date:_____

Entered to eCRF ☐ Initials _____

FORM NO. CNA042

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: _____/_____/_____ 2=Life Threatening 3=Requires or Prolongs Inpatient Hospitalization 4=Persistent or Significant Disability or Incapacity 5=Congenital Anomaly/Birth Defect 6=Other Serious (Important Medical Events)	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	Expectedness	Severity	Relationship to Study/Study Product	Outcome Attributed to SAE	Study Status	Narrative added* (progress note)
1.										☐
2.										☐
3.										☐
4.										☐
5.										☐

* Narrative should include the following: detailed description of event, problem, and/or product use error, and relevant tests/laboratory data, including dates

PI Signature_____ Date:_____

RNC Signature_____ Date:_____

Entered to eCRF ☐ Initials _____

FORM NO. CNA043		
Is this unanticipated problem specific to an individual subject ?	☐ Yes	☐ No
Acrostic Identifier: *(fill in if answer to above is "Yes")*		
Study ID: *(fill in if answer to above is "Yes")*		
Site: *(fill in if answer to above is "No")*		
(Note: If the UP does not apply to an individual subject, the Acrostic Identifier and Study ID remain blank)		
Date form completed: _____/_____/_____		

Unanticipated Problem (UP) Report

Definition of an UP: Any problem or event which in the opinion of the local researcher was unanticipated, serious and at least possibly related to the research procedures.

These should be reported to the IRB within 10 working days.

Date of the Event: _____/_____/_____

Date the site study team had knowledge of the Event: _____/_____/_____

This Event meets the criteria for an unanticipated problem because:

☐	1	**Unanticipated:** The event is unexpected in terms of nature, severity or frequency given the research procedures described in the protocol, consent, etc. or given the characteristics of the population being studied.
☐	2	**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	**Serious:** The event placed subjects or others at greater risk (including physical, psychological, economic, or social harm) that was previously known or recognized or resulted in harm to the subject or others.

Note: The event must meet all of the above criteria to be considered an unanticipated problem.

Describe the type of event:

☐	Accidental or unintentional change to the IRB-approved protocol that resulted in risk or has the potential to recur.
☐	Publication in the literature, safety monitoring report, or other findings indicating an unexpected change to the risks or potential benefits of the research.
☐	Complaint of a participant that indicates an unanticipated risk or which cannot be resolved by the research staff.
☐	A breach in confidentiality that may involve risk to that individual or others (e.g. compromised/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 _____

FORM NO.CNA044		
Acrostic Identifier:		
Study ID:		
Date form completed: _____/_____/_____		
Protocol Deviation/Violation Report		
Date of the Event: _____/_____/_____ ☐ Event has not yet occurred (exemption request)		
Date the site study team had knowledge of the Event: _____/_____/_____		
This Event meets the criteria for a protocol deviation/violation because:		
☐	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 <u>must meet at least one</u> of the above criteria to be considered a protocol deviation/violation.		
Describe the protocol deviation/violation:		
Explain why or how the deviation/violation occurred:		
Indicate the outcome (PI's assessment of the outcome, comments, or determinations):		
Describe what action you have taken to prevent recurrence:		

PI Signature_____ Date:_____

RNC Signature_____ Date:_____

Entered to eCRF Initials _____

CCTRN Exemption/Waiver Documentation (DCC only)	
CCTRN Medical Officer or Designee Review:	
Action Taken:	☐ **Granted** ☐ **Not Granted**
Waiver Acknowledgement:	☐ **Received / Acknowledged**

DCC Signature_____ Date:_____

FORM NO. CNA048	
Acrostic Identifier:	
Study ID:	

Missing Form

	Form Missing:	Reason/Comment:	Date of this Report:
☐	Baseline Risk Factors & Other Cardiac Hx		
☐	Baseline Non Cardio. Med. Hx		
☐	Baseline - Physical Exam		
☐	Baseline - ECG		
☐	Baseline - Labs		
☐	Baseline - Qual. of Life MLHF		
☐	Baseline - Qual. of Life SF-36		
☐	Baseline - 6 minute walk test		
☐	Baseline - Holter		
☐	Medication allergies		
☐	Medication list		
☐	Bone Marrow Aspiration		
☐	Study Product Injection		
☐	Day of Injection - Phys. Exam		
☐	Day of Injection - ECG		
☐	Day of Injection - Holter		
☐	Day after Injection - Phys. Exan		
☐	Day after Injection - ECG		
☐	Day after Injection - 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		

FORM NO. CNA048	
Acrostic Identifier:	
Study ID:	

Missing Form

	Form Missing:	Reason/Comment:	Date of this Report:
☐	Mo 3 - Labs		
☐	Mo 3 - Holter		
☐	Mo 3 - ECG		
☐	Mo 3 - Qual. of Life MLHF		
☐	Mo 3 - Qual. of Life SF-36		
☐	Mo 6 - Physical Exam		
☐	Mo 6 - Labs		
☐	Mo 6 - ECG		
☐	Mo 6 - Holter		
☐	Mo 6 - 6 minute walk test		
☐	Mo 6 - Qual. of Life MLHF		
☐	Mo 6 - Qual. of Life SF-36		
☐	Mo 12 - Physical Exam		
☐	Mo 12 - Labs		
☐	Mo 12 - ECG		
☐	Mo 12 - Qual. of Life MLHF		
☐	Mo 12 - Qual. of Life SF-36		
☐	Mo 24 - F/U Phone Contact		
☐	Mo 36 - F/U Phone Contact		
☐	Mo 48 - F/U Phone Contact		
☐	Mo 60 - F/U Phone Contact		
☐	End of Study		

FORM NO. CNA051	
Acrostic Identifier:	
Study ID:	

Date source form completed: _____/_____/_____

End of Study

Date of final follow-up study visit: _____/_____/_____

Reason for discharge from the study:

- ☐ Completed study — Date: _____/_____/_____
- ☐ Withdrawn — Date: _____/_____/_____
- ☐ Lost to follow-up — Date: _____/_____/_____
- ☐ Screen Failure — Date: _____/_____/_____

If "Withdrawn", please check the primary reason for withdrawal:

Reasons that require follow-up:

- ☐ Serious Adverse Event (until resolved) — Event Number:
- ☐ Pregnancy (1 year post birth) — Event Number:
- ☐ Other — Describe:

Reasons that DO NOT require follow-up:

- ☐ Death — Event Number:
- ☐ Adverse Event — Event Number:
- ☐ Withdrawal of consent
- ☐ Protocol Deviation/Violation
- ☐ Investigator Discretion — Describe:
- ☐ Sponsor Discretion — Describe:
- ☐ Other — Describe:

Please verify the following tasks are complete:

☐	All Informed Consents forms are properly signed/dated and available
☐	Hard copy workbooks are signed, dated and present in the CCTRN source document patient binder; workbooks may be grouped by a visit with one signature per visit.
☐	All source document data have been entered into the electronic CRF database
☐	All electronic CRFs have been submitted to the DCC
☐	I have reviewed all case report forms for this patient and found them to be in complete agreement with the source documents.
☐	If any questions arise from the DCC data review (due to missing, unclear, or incorrect entries), the authorized staff will supply appropriate corrections.

PI Signature _____ Date:

Entered to eCRF ☐ Initials _____

FORM NO. CNA005	
Acrostic Identifier:	
Study ID:	
Date source form completed: _____/_____/_____	

Physical Exam - *Week 1*

Date of Exam: _____/_____/_____	☐ **Visit is outside time window**	**Reason:**

☐ **Informed consent was revised since study start date**

Date patient reconsented: ___/___/____ **Consent version:**

Vital Signs		**NYHA Class:**	**CCS Class:**
Weight:	_____ pounds	☐ I	☐ I
Temperature:	_____°F ☐oral ☐auricle	☐ II	☐ II
Respirations:	__ __ breaths/minute	☐ III	☐ III
Heart rate:	__ __ __ beats/minute	☐ IV	☐ IV
Blood Pressure:	__ __ __ / __ __ __ mmHg (supine) SBP DBP	☐ N/A	☐ N/A

Review of Systems:

Have changes occurred since previous visit? Yes ☐ No ☐ If no, table is complete.

Organs	Normal	Abnormal	Not Examined	Describe
Skin	☐	☐	☐	
HEENT	☐	☐	☐	
Lungs	☐	☐	☐	
CV	☐	☐	☐	
Abdomen	☐	☐	☐	
Lymph Nodes	☐	☐	☐	
Musculoskeletal	☐	☐	☐	
Neurological	☐	☐	☐	
Other: _____	☐	☐	☐	

Questions

Has the patient experienced a new adverse event since last visit? (If yes, complete AE form)	Yes ☐ No ☐	
Have there been any significant changes in physical findings since last visit? (If yes, please explain in comments)	Yes ☐ No ☐	
Have there been any changes to medications since last visit? (If yes, update medication form)	Yes ☐ No ☐	
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 ☐

FORM NO. CNA005	
Acrostic Identifier:	
Study ID:	
Date source form completed: _____/_____/_____	

Physical Exam - *Week 1*

Questions	
Was a routine no contrast Echo completed? (If not done, or if result abnormal, please explain in comments)	Yes ☐ No ☐ Normal ☐ Abnormal ☐
Has there been a change in nitrate usage since last visit? (If yes, please update medication 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 completed: _____/_____/_____			
Laboratory Tests - *Week 1*			
Date and time specimen obtained: **Date:** _____/_____/_____ **Time:** __ __:__ __			
CBC with Differential	**Result**	**Unit**	**Normal Range**
WBC		K/mm^3	4.0-11.0 K/mm^3
RBC		M/mm^3	4.0-6.0 M/mm^3
Hgb		gm/dL	12.0-17.5 gm/dL
Hct		%	33-53%
MCV		fL	78-100 fL
Platelets		K/mm^3	135-450 K/mm^3
WBC Differential			
Neutrophilis		%	36-74%
Lymphocytes		%	12-45%
Monocytes		%	0-13%
Eosinophils		%	0-8%
Basophils		%	< 3.0%
Cardiac Markers (Either Troponin T or Troponin I should 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			
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

FORM NO. CNA021			
Acrostic Identifier:			
Study ID:			
Date source form completed: _____/_____/_____			
Laboratory Tests - *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 ☐ Initials _____

FORM NO. CNA023

Acrostic Identifier:	
Study ID:	

Date source/workbook completed: _____/_____/_____

Holter Data Form - *Week 1*

Date procedure started: _____/_____/_____

Total recording time: __ __:__ __

General:

Total beats/QRS Complexes: __ __ __ __ __ __ beats

Paced beats: __ __ __ __ __ __ beats

Pauses/Longest RR Interval (> 2 secs):

Longest pause was __ __ seconds @ __ __:__ __

Total number of pauses: __ __ __

Predominant Rhythm: *(mutually exclusive)*

☐ Sinus Rhythm ☐ Junctional Rhythm

☐ Paced Rhythm ☐ Ectopic Atrial Rhythm

☐ Atrial Flutter / Fibrillation

Heart Rates:

Minimum: __ __ __beats/min. @ __ __:__ __

Average: __ __ __beats/min.

Maximum: __ __ __beats/min. @ __ __:__ __

Ventricular Arrhythmia Summary:

Single/PVC: __ __ __ __ __ __ beats

Couplets: __ __ __ __ __ __

Total number of NSVT Runs (≥ 3 beats) __ __ __

Number of beats in longest NSVT run __ __ __

Total number of sustained ventricular tachycardia runs (≥ 30 secs) __ __ __

Supraventricular Arrhythmia Summary:

Single/PAC: __ __ __ __ __ __ beats

Couplets: __ __ __ __ __ __

Total number of SVT Runs __ __ __

Number of beats in longest SVT run __ __ __

Intermittent Atrial Fibrillation / Atrial Flutter:

☐ 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

__ __ __ total no. of episodes __ __ __ __ __ duration of longest episode (secs)

Comments:

PI Signature: _____ Date: _____

Entered to eCRF ☐ 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.__ __ 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
- ☐ sinus arrhythmia
- ☐ sinus bradycardia (<60 bpm)
- ☐ sinus tachycardia (>100 bpm)
- ☐ atrial fibrillation
- ☐ atrial flutter
- ☐ multifocal atrial tachycardia
- ☐ supraventricular tachycardia
- ☐ junctional tachycardia
- ☐ ventricular bigeminy
- ☐ ectopic atrial rhythm
- ☐ ventricular demand pacemaker (VVI)
- ☐ atrial pacemaker
- ☐ dual chamber pacemaker (DDD)
- ☐ wandering pacemaker
- ☐ accelerated idioventricular rhythm
- ☐ atrial premature complexes
- ☐ ventricular premature complexes (PVCs)
- ☐ ventricular couplets
- ☐ junctional rhythm
- ☐ ventricular fibrillation
- ☐ 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 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 enlargement

Abnormalities of QRS axis: (Choose one) ☐ **NONE**

- ☐ Left axis deviation(> -30º)
- ☐ Right axis deviation (> +100º)

QRS voltage abnormalities: (Choose all that apply) ☐ **NONE**

- ☐ Low voltage
- ☐ Left ventricular hypertrophy
- ☐ Right ventricular hypertrophy

FORM NO. CNA024	
Acrostic Identifier:	
Study ID:	

Date source form completed: _____/_____/_____

ECG - *Week 1*

Intraventricular conduction abnormalities: (Choose all that apply) ☐ **NONE**

- ☐ Right bundle branch block, complete
- ☐ Right bundle branch block, incomplete
- ☐ Left anterior fascicular block
- ☐ Left posterior fascicular block
- ☐ Left bundle branch block, complete
- ☐ Left bundle branch block, incomplete
- ☐ Nonspecific intraventricular conduction disturbance

			For each "Yes" response, check all locations that apply:		
Are Q waves present?	Y ☐	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?	Y ☐	N ☐	Anterior ☐	Lateral ☐	Inferior ☐
Is there evidence of posterior infarction?	Y ☐	N ☐	Pathologic wave V_2 ☐	R V_1, Abn. ST depression V_1, V_2 ☐	Abn. ST elevation V_1, V_2 ☐
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 _____

FORM NO. CNA005	
Acrostic Identifier:	
Study ID:	
Date source form completed: _____/_____/_____	

Physical Exam - *Week 4*

Date of Exam: ____/____/____	☐ **Visit is outside time window**	**Reason:**

☐ **Informed consent was revised since study start date**

Date patient reconsented: ___/___/____ **Consent version:**

Vital Signs		**NYHA Class:**	**CCS Class:**
Weight:	_____ pounds	☐ I	☐ I
Temperature:	_____°F ☐oral ☐auricle	☐ II	☐ II
Respirations:	__ __ breaths/minute	☐ III	☐ III
Heart rate:	__ __ __ beats/minute	☐ IV	☐ IV
Blood Pressure:	__ __ __ / __ __ __ mmHg (supine) SBP DBP	☐ N/A	☐ N/A

Review of Systems:

Have changes occurred since previous visit? Yes ☐ No ☐ If no, table is complete.

Organs	Normal	Abnormal	Not Examined	Describe
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)	Yes ☐ No ☐
Have there been any significant changes in physical findings since the last follow-up visit? (If yes, please explain in comments)	Yes ☐ No ☐
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 completed: _____/_____/_____	

Physical Exam - *Week 4*

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? (If no, please explain in the Comments) **Verify patient consented to Biorepository before you draw Biorepository bloods.**	Yes ☐ No ☐	
Has there been a change in nitrate usage since the last follow-up visit? (If yes, please update medication 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 completed: _____/_____/_____			
Laboratory Tests - *Week 4*			
Date and time specimen obtained: Date: ____/____/____ Time: __ __:__ __			
CBC with Differential	**Result**	**Unit**	**Normal Range**
WBC		K/mm^3	4.0-11.0 K/mm^3
RBC		M/mm^3	4.0-6.0 M/mm^3
Hgb		gm/dL	12.0-17.5 gm/dL
Hct		%	33-53%
MCV		fL	78-100 fL
Platelets		K/mm^3	135-450 K/mm^3
WBC Differential			
Neutrophilis		%	36-74%
Lymphocytes		%	12-45%
Monocytes		%	0-13%
Eosinophils		%	0-8%
Basophils		%	< 3.0%
Cardiac Markers (Either Troponin T or Troponin I should 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			
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

FORM NO. CNA021			
Acrostic Identifier:			
Study ID:			
Date source form completed: _____/_____/_____			
Laboratory Tests - *Week 4*			
Other Tests			
BNP		pg/ml	0-100 pg/ml
hsCRP		mg/L	0.0-40 mg/L
Pregnancy Test (women of 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/workbook completed: _____/_____/_____

Holter Data Form - *Week 4*

Date procedure started: _____/_____/_____

Total recording time: __ __:__ __

General:

Total beats/QRS Complexes: __ __ __ __ __ __ beats

Paced beats: __ __ __ __ __ __ beats

Pauses/Longest RR Interval (> 2 secs):

Longest pause was __ __ seconds @ __ __:__ __

Total number of pauses: __ __ __

Predominant Rhythm: *(mutually exclusive)*

☐ Sinus Rhythm ☐ Junctional Rhythm

☐ Paced Rhythm ☐ Ectopic Atrial Rhythm

☐ Atrial Flutter / Fibrillation

Heart Rates:

Minimum: __ __ __beats/min. @ __ __:__ __

Average: __ __ __beats/min.

Maximum: __ __ __beats/min. @ __ __:__ __

Ventricular Arrhythmia Summary:

Single/PVC: __ __ __ __ __ __ beats

Couplets: __ __ __ __ __ __

Total number of NSVT Runs (≥ 3 beats) __ __ __

Number of beats in longest NSVT run __ __ __

Total number of sustained ventricular tachycardia runs (≥ 30 secs) __ __ __

Supraventricular Arrhythmia Summary:

Single/PAC: __ __ __ __ __ __ beats

Couplets: __ __ __ __ __ __

Total number of SVT Runs __ __ __

Number of beats in longest SVT run __ __ __

Intermittent Atrial Fibrillation / Atrial Flutter:

☐ 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

__ __ __ total no. of episodes __ __ __ __ __ duration of longest episode (secs)

Comments:

PI Signature: _____ Date: _____

Entered to eCRF ☐ Initials _____

FORM NO. CNA024	
Acrostic Identifier:	
Study ID:	

Date source form completed: _____/_____/_____

ECG - *Week 4*

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
- ☐ sinus arrhythmia
- ☐ sinus bradycardia (<60 bpm)
- ☐ sinus tachycardia (>100 bpm)
- ☐ atrial fibrillation
- ☐ atrial flutter
- ☐ multifocal atrial tachycardia
- ☐ supraventricular tachycardia
- ☐ junctional tachycardia
- ☐ ventricular bigeminy
- ☐ ectopic atrial rhythm
- ☐ ventricular demand pacemaker (VVI)
- ☐ atrial pacemaker
- ☐ dual chamber pacemaker (DDD)
- ☐ wandering pacemaker
- ☐ accelerated idioventricular rhythm
- ☐ atrial premature complexes
- ☐ ventricular premature complexes (PVCs)
- ☐ ventricular couplets
- ☐ junctional rhythm
- ☐ ventricular fibrillation
- ☐ 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 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 enlargement

Abnormalities of QRS axis: (Choose one) ☐ **NONE**

- ☐ Left axis deviation(> -30º)
- ☐ Right axis deviation (> +100º)

QRS voltage abnormalities: (Choose all that apply) ☐ **NONE**

- ☐ Low voltage
- ☐ Left ventricular hypertrophy
- ☐ Right ventricular hypertrophy

FORM NO. CNA024	
Acrostic Identifier:	
Study ID:	
Date source form completed: _____/_____/_____	

ECG - *Week 4*

Intraventricular conduction abnormalities: (Choose all that apply) ☐ **NONE**

- ☐ Right bundle branch block, complete
- ☐ Right bundle branch block, incomplete
- ☐ Left anterior fascicular block
- ☐ Left posterior fascicular block
- ☐ Left bundle branch block, complete
- ☐ Left bundle branch block, incomplete
- ☐ Nonspecific intraventricular conduction disturbance

			For each "Yes" response, check all locations that apply:		
Are Q waves present?	Y ☐	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?	Y ☐	N ☐	Anterior ☐	Lateral ☐	Inferior ☐
Is there evidence of posterior infarction?	Y ☐	N ☐	Pathologic wave V_2 ☐	R V_1, Abn. ST depression V_1, V_2 ☐	Abn. ST elevation V_1, V_2 ☐
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 _____