FORM NO. CNC005

Acrostic Identifier:

Study ID:

Date form completed: ____/____/____

Physical Exam *(Day of Infusion)*

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

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

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

Review of Systems:

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

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

FORM NO. CNC005	
Acrostic Identifier:	
Study ID:	
Date form completed: ____/____/____	
Physical Exam *(Day of Infusion)*	
Questions	
Has the patient experienced any adverse events? (If yes, complete AE form)	Yes ☐ No ☐
Have there been any changes to medications? (If yes, update medication form)	Yes ☐ No ☐
Was the "Day 0" MRI completed and results sent to the Core Lab? (If no, please explain in the Comments)	Yes ☐ No ☐
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 ☐
Was one 3 ml yellow top tube (anti-coagulated with acid citrate dextrose) for preparation/blinding of the placebo product drawn and sent to the cell processing lab? (If no, please explain in the Comments)	Yes ☐ No ☐
Comments:	

☐ Entered to eCRF Initials _____

FORM NO. CNC029	
Acrostic Identifier:	
Study ID:	
Date 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. CNC031			
Acrostic Identifier:			
Study ID:			
Date form completed: ____/____/_____			
Vital Signs Pre-Cath (Pre-Study Product Infusion)			
Date: ____/____/____ Time: __ __:__ __			
Temperature:	_____°F ☐ oral ☐ auricle		
Respirations:	__ __ breaths/minute		
Heart rate:	__ __ __ beats/minute		
Blood Pressure:	__ __ __ / __ __ __ SBP DBP	mmHg (supine)	
Study Product Infusion Period			
Procedure Start Time: __ __:__ __	Stop Time: __ __:__ __		
Was the revascularized vessel patent at the time of cell administration?	No ☐	Yes ☐	If no, pt is ineligible for continuation; fill out an AE and End of Study form
ST segment changes?	No ☐	Yes ☐	
Nitroglycerin given?	No ☐	Yes ☐	Amount: __ __ __ mcg (IC)
Heparin given?	No ☐	Yes ☐	Amount: __ __ __ units
Infusion Catheter Information:			
Manufacturer:			
Model Name:			
Model Number:			
Diameter: mm			
Infusion 1 Start Date: ___/___/___	Start Time: __ __:__ __	Volume of infusion 1: __ __ ml	
Stop Date: ___/___/___	Stop Time: __ __:__ __	☐ Not done	
Infusion 2 Start Date: ___/___/___	Start Time: __ __:__ __	Volume of infusion 2: __ __ ml	
Stop Date: ___/___/___	Stop Time: __ __:__ __	☐ Not done	
Infusion 3 Start Date: ___/___/___	Start Time: __ __:__ __	Volume of infusion 3: __ __ ml	
Stop Date: ___/___/___	Stop Time: __ __:__ __	☐ Not done	
Infusion 4 Start Date: ___/___/___	Start Time: __ __:__ __	Volume of infusion 4: __ __ ml	
Stop Date: ___/___/___	Stop Time: __ __:__ __	☐ Not done	
Infusion 5 Start Date: ___/___/___	Start Time: __ __:__ __	Volume of infusion 5: __ __ ml	
Stop Date: ___/___/___	Stop Time: __ __:__ __	☐ Not done	
Infusion 6 Start Date: ___/___/___	Start Time: __ __:__ __	Volume of infusion 6: __ __ ml	
Stop Date: ___/___/___	Stop Time: __ __:__ __	☐ Not done	

FORM NO. CNC031		
Acrostic Identifier:		
Study ID:		
Date form completed: ____/____/_____		
Vital Signs Post-Cath (Post-Study Product Infusion)		
Date: ____/____/_____ Time: __ __:__ __		
Temperature:	_____°F ☐ oral ☐ auricle	
Respirations:	__ __ breaths/minute	
Heart rate:	__ __ __ beats/minute	
Blood Pressure:	__ __ __ / __ __ __ mmHg (supine) SBP DBP	
Questions		
1. Was the procedure prematurely stopped? (If yes, complete AE or SAE, and/or UP form)	Yes ☐	No ☐
2. Was the procedure restarted?	Yes ☐	No ☐ N/A ☐
3. Did the patient experience an adverse event during the procedure? (If yes, complete AE or SAE form)	Yes ☐	No ☐
4. Were concomitant medications given? (If yes, add to Medication form)	Yes ☐	No ☐
Comments:		

Entered to eCRF ☐ Initials _____

FORM #	DESCRIPTION of LateTIME FORMS	LateTIME Excel Wkbk tab name
CNC099	Screening/Demographics	Enrollmt
CNC001	Eligibility	Elig
CNC003	Baseline Risk Factors & Other Cardiac Hx	Risk
CNC004	Baseline Non Cardio. Med. Hx	Med Hx
CNC005	Physical Exams	BSL PE/PE
CNC006	Index Event (Revascularization)	PCI
CNC007	Treatment Checklist	Treatment
CNC011	Medication List	Meds
CNC012	Medication Allergies	Meds
CNC021	Labs (Panels)	BSL Labs/D1 Labs
CNC022	Labs (F/U)	Labs M 6,12,24
CNC023	Holter	Holter
CNC024	ECG	ECG
CNC026	Labs (Interim)	Interim Labs
CNC029	Bone Marrow Aspiration	Aspir
CNC031	Study Product Infusion	SPI
CNC041	Adverse Event	AE
CNC042	Serious Adverse Event	SAE
CNC043	Unanticipated Problem	UP
CNC044	Protocol Deviation	Prot Dev
CNC045	Schedule of Procedures	Sched
CNC047	Data Glossary	Glossary
CNC048	Missing Form	Missing
CNC051	End of Study	End

FORM NO. CNC045	
Acrostic Identifier:	
Study ID:	
Schedule of Procedures Late TIME	
Procedures	**Target Date (Window)**
Screening/Baseline	
Screen/Demographics Eligibility (Inclusion/Exclusion criteria) Revascularization/PCI Baseline PE Baseline Lab Panels Baseline Non-Cardiovascular History Baseline Risk Factors Baseline Allergies Baseline Medications Baseline ECG Baseline Echo (core) Treatment Checklist	
Aspiration/Infusion (SPI)	**MI + 14 to 21 days**
Day of Infusion PE Biorepository blood draws (if consented) Bone Marrow Aspiration Baseline cMRI (core) Cell Processing Cell Processing - Post Release Study Product Infusion	
Day after Infusion	**SPI +1**
Day after Infusion PE Biorepository blood draws (if consented) Day after Infusion Lab Panels Day after Infusion ECG	
1 Month	**SPI + 30 days +/- 7 days**
PE Labs (F/U) Biorepository blood draws (if consented) ECG Holter	
3 Month	**SPI + 90 days +/- 14 days**
PE Labs (F/U) Biorepository blood draws (if consented)	
6 Month	**SPI + 180 days +/- 30 days**
PE Labs (F/U) ECG Biorepository blood draws (if consented) Echo (core) cMRI (core)	

FORM NO. CNC045	
Acrostic Identifier:	
Study ID:	
Schedule of Procedures Late TIME	
Procedures	**Target Date (Window)**
12 Month	**SPI + 365 days +/- 30 days**
PE Labs (F/U) cMRI	
24 Month	**SPI + 730 days +/- 30 days**
PE Labs (F/U) cMRI End of Study	

cMRI:

- echo at 12 & 24 months if cMRI is contraindicated

Laboratory tests:

- *baseline:* CBC/diff, lipid panel, renal panel, hepatic panel, CK, CK-MB, troponin T or I, BNP, hsCRP, pregnancy test for childbearing females (For Late TIME, all but hsCRP and pregnancy test will be done as part of routine care)
- *Day 1:* CBC/diff, renal panel, hepatic panel, [CK, CK-MB, troponin T or I one time on the morning following the infusion]
- *Mo 1,3:* CBC/diff, hepatic panel
  Mo 6,12,24: CBC/diff, hepatic panel, & BNP

FORM NO. CNC099		
Date source/workbook 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. CNC001		
Acrostic Identifier:		
Study ID:		
Date source/workbook completed: ____/____/_____		Date of PCI: _____/_____/_____
Eligibility Criteria		
Note: The use of either DES or BMS for percutaneous revascularization of the infarct-artery is required. The revascularized vessel must be patent at the time cell administration is to be attempted.		
Y	**N**	**Inclusion Criteria (Must answer Yes to all questions to be eligible)**
☐	☐	Patient is at least 21 years of age
☐	☐	First MI with successful primary PCI in an artery at least 2.5 mm in diameter occurring two to three weeks before recruitment
☐	☐	No contraindications to undergoing cell therapy procedure within two to three weeks post AMI and PCI
☐	☐	Hemodynamic stability as defined as not requiring IABP, inotropic or blood pressure supporting medications
☐	☐	Ejection fraction following reperfusion with PCI ≤ 45% as assessed by echocardiography
☐	☐	Consent signed. Date signed ____/___/____
☐	☐	Women of childbearing potential willing to use an active form of birth control (If male, check "Y")
Y	**N**	**Exclusion Criteria (Must answer No to all questions to be eligible)**
☐	☐	History of sustained ventricular arrhythmias not related to AMI (evidenced by previous Holter monitoring and/or medication history for sustained ventricular arrhythmias in patient's medical chart)
☐	☐	Requires CABG or PCI due to the presence of residual coronary stenosis >70% luminal obstruction in the non-infarct related vessel (Additional PCI of non-culprit vessels may be performed prior to enrollment)
☐	☐	History of any malignancy within the past 5 years excluding non-melanoma skin cancer or cervical cancer *in-situ*
☐	☐	History of chronic anemia (hemoglobin (Hgb) < 9.0 mg/dl)
☐	☐	History of thrombocytosis (platelets > 500k)
☐	☐	Baseline platelet count (prior to revascularization) <120,000 or known history of thrombocytopenia
☐	☐	Known history of elevated INR (PT) or PTT
☐	☐	Life expectancy less than one year
☐	☐	History of untreated alcohol or drug abuse
☐	☐	Currently enrolled in another investigational drug or device trial
☐	☐	Previous CABG
☐	☐	Previous MI with resultant LVEF < 55%
☐	☐	History of stroke or TIA within the past 6 months
☐	☐	History of severe valvular heart disease (aortic valve area < 1.0 cm^2 or > 3+ mitral regurgitation)

FORM NO. CNC001		
Acrostic Identifier:		
Study ID:		
Eligibility Criteria		
Y	**N**	**Exclusion Criteria continued (Must answer No to all questions to be eligible)**
☐	☐	Pregnant or breast feeding
☐	☐	Has a known history of HIV, or has active Hepatitis B or C infection, or active TB
☐	☐	Has an active inflammatory or autoimmune disease on chronic immunosuppressive therapy
☐	☐	Contraindications to cMRI
☐	☐	Previous radiation to the pelvis with WBC and platelet counts below hospital-specific normal values
☐	☐	Women of childbearing potential not willing to use an active form of birth control (If male, check "N")
☐	☐	Chronic liver disease that might interfere with survival or treatment with cell therapy
☐	☐	Chronic renal insufficiency as defined by a creatinine ≥ 2.0 mg/dl or requires chronic dialysis
☐ 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		
Comments:		

PI Signature_____ Date:_____

RNC Signature_____ Date:_____

Entered to eCRF ☐ Initials _____

FORM NO. CNC003						
Acrostic Identifier:						
Study ID:						
Date source/workbook 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 ☐			
Family Hx of MI	No ☐		Yes ☐		Unknown ☐	
Angina	No ☐		Stable ☐		Unstable ☐	
Carotid Disease, asymptomatic	No ☐		Yes ☐			
Hx of TIAs	No ☐		Yes ☐			
Hx of valvular heart disease	No ☐		Yes ☐			
If yes, check all that apply:			mitral ☐			
			aortic ☐			
			pulmonic ☐			
			tricuspid ☐			
Hx of aneurysm	No ☐		Yes ☐			
Hx of Stroke	No ☐		current deficit ☐		completely resolved ☐	
Hx of PVD	No ☐		Yes ☐			
Obese or Hx of obesity	No ☐		Yes ☐			
Smoking	Never ☐		Previous ☐ Yr stopped: _____		Current ☐ packs/day: __	

FORM NO. CNC003					
Acrostic Identifier:					
Study ID:					
Date source/workbook completed: ____/____/_____					
Baseline Risk Factors					
Other Cardiac History					
Prior to this hospitalization, have you been hospitalized for:					If yes, Date of most recent
Congestive Heart Failure	No	☐	Yes	☐	____/____/____
Revascularizations (non-CABG)	No	☐	Yes	☐	____/____/____
Previous MI	No	☐	Yes	☐	____/____/____
Bypass surgery (CABG)	No	☐	Yes	☐	____/____/____
Cardiac catheterization	No	☐	Yes	☐	____/____/____
Cardiac pacemaker	No	☐	Yes	☐	____/____/____
Other coronary interventions	No	☐	Yes	☐	
If yes, please describe other coronary interventions:					
Procedure:					**Date most recent:**
1.					____/____/____
2.					____/____/____
3.					____/____/____
Comments:					

Entered to eCRF ☐ Initials _____

FORM NO. CNC004				
Acrostic Identifier:				
Study ID:				
Date source/workbook 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. CNC012			
Acrostic Identifier:			
Study ID:			
Date source/workbook completed: ____/____/_____			
Medication Allergies			
Drug Allergies	NKDA ☐	Yes ☐	Please list:

FORM NO. CNC011									
Acrostic Identifier:									
Study ID:									
Date form completed: _____/_____/_____									
Medications									
	Medication Class	Medication Name	Dose	Unit	Frequency	Prior to Study Start	Start Date	Stop Date	Comments
1						☐			
2						☐			
3						☐			
4						☐			
5						☐			
6						☐			
7						☐			
8						☐			
9						☐			
10						☐			
11						☐			
12						☐			
13						☐			
14						☐			
15						☐			
16						☐			
17						☐			
18						☐			

Entered to eCRF ☐ Initials _____

Medication eCRF drop down lists:

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. CNC024

Acrostic Identifier:

Study ID:

Date source/workbook 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. CNC024

Acrostic Identifier:

Study ID:

Date source/workbook 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_1, 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 ☐	/A ☐		
Are there nonspecific ST and/or T wave abnormalities present?	Y ☐	N ☐			

Comments:

PI Signature_____ Date:_____

Entered to eCRF ☐ Initials _____

FORM NO. CNC006					
Acrostic Identifier:					
Study ID:					
Date source/workbook completed: ____/____/_____					
Revascularization / PCI					
Date of onset of chest pain:	____/____/____	Time: __ __:__ __			
Date patient presented at ER:	___/___/_____	Time: __ __:__ __			
Date of PCI:	____/____/____	Time: __ __:__ __			
Calculated ischemic period:	*(program calculates time between onset of chest pain and PCI)*				
Calculated door-to-ballon time:	*(program calculates time between presented at ER and PCI)*				
TIMI Flow & TMP scores	Pre PCI: _____	Post PCI: _____			
Artery Location of PCI (Select all that apply)			**Stent Type**		
Artery:	No	Yes	None	Drug eluting	Bare metal
Circumflex	☐	☐	☐	☐	☐
RCA	☐	☐	☐	☐	☐
LAD	☐	☐	☐	☐	☐
Note: If more than one stent is placed in an artery, please state the number of stents per location(s) in the Comments section.					
Comments:					
Entered to eCRF ☐ Initials _____					

FORM NO. CNC005

Acrostic Identifier:

Study ID:

Date source/workbook completed: ____/____/_____

Physical Exam *(Baseline)*

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

Vital Signs		**NYHA Class:**
Height:	_____ inches	☐ I
Weight:	_____ pounds	☐ II
Temperature:	__ __.__°F ☐ oral ☐ auricle	☐ III
Respirations:	__ __ breaths/min	☐ IV
Heart rate:	__ __ __ beats/min	☐ N/A
Blood Pressure:	__ __ __ / __ __ __ mmHg (supine) SBP DBP	**LVEF:** __ __ **%** (screening echo) Was there evidence of LV thrombus on the screening echo? ☐ Yes ☐ No

Review of Systems:

Organs	Normal	Abnormal	Not Examined	Describe *(must describe if answer abnormal)*
Skin	☐	☐	☐	
HEENT	☐	☐	☐	
Lungs	☐	☐	☐	
CV	☐	☐	☐	
Abdomen	☐	☐	☐	
Lymph Nodes	☐	☐	☐	
Musculoskeletal	☐	☐	☐	
Neurological	☐	☐	☐	
Other: _____	☐	☐	☐	

Questions

Has the patient experienced any adverse events? (If yes, complete AE form)	Yes ☐ No ☐
Was the baseline echo completed to send to the Core Lab? (If no, please enter a reason in Comments)	Yes ☐ No ☐
Comments:	

Entered to eCRF Initials _____

FORM NO. CNC021			
Acrostic Identifier:			
Study ID:			
Date source/workbook 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 Enzymes (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
Renal Panel			
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
Creatine		mg/dL	0.4-1.5 mg/dL
Albumin		g/dL	3.5-5.0 gm/dL
Calcium		mg/dL	8.0-10.6 mg/dL
Inorganic Phosphorus		mg/dL	2.5-4.7 mg/dL

FORM NO. CNC021			
Acrostic Identifier:			
Study ID:			
Date source/workbook completed: ____/____/_____			
Laboratory Tests (Baseline)			
Hepatic Panel			
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
Lipid Panel			
Cholesterol		mg/dL	100-240 mg/dL
Triglycerides		mg/dL	0-200 mg/dL
HDL Cholesterol		mg/dL	32-95 mg/dL
Calculated LDL		mg/dL	60-129 mg/dL
Chol / HDL Ratio			0-4.5
Other Tests			
BNP		pg/ml	0-100 pg/ml
hsCRP		mg/L	0.0-40 mg/L
Pregnancy Test (women of childbearing age) ☐ Not applicable age or gender			Negative (urine) < 5.0 mU/ml (quantitative blood)
Comments:			

PI Signature_____ Date:_____

Entered to eCRF ☐ Initials _____

FORM NO. CNC007

Acrostic Identifier:

Study ID:

Treatment Checklist

Date source/workbook completed: ____/____/_____

Please enter a Value from the previously completed Screening/Demographics, Eligibility, Baseline Physical Exam, Baseline Laboratory Tests and Baseline ECG Forms:

Variable	Value	Criteria
Patient Age		Must be ≥ 21 years old at consent date
LVEF		Must be ≤ 45%
Temperature		Must be < 100.4 ºF
Hemoglobin		Must be ≥ 9.0 mg/dl
Platelets*		Must be ≥ 120K and ≤ 500K BEFORE revascularization*
Creatinine		Must be < 2.0 mg/dl
LV thrombus evidence		
Atrial Fibrillation		

If any of the variables above have changed since the Baseline Physical Exam or Baseline Lab Tests, and a more recent exam or test has been done, please enter the updated value, date, and time of the re-check. *Use a platelet count BEFORE revascularization. If the platelet count above was post-revascularization, please enter a pre-revascularization count, test date and time below.

Variable	Value	Date	Time
LVEF		____/____/____	
Temperature		____/____/____	
Hemoglobin		____/____/____	
Platelets*		____/____/____	
Creatinine		____/____/____	

☐ A baseline testing exemption has been granted by the CCTRN Medical Monitor for one or more of the above variables, excluding LV thrombus or Afib (comment required with a brief explanation; include detail if multiple variables are involved). **Answers to questions below cannot be overridden by checking this box.**

FORM NO. CNC007		
Acrostic Identifier:		
Study ID:		
Treatment Checklist		
Please answer the following questions:		
1. 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 ☐
2. Is there any other reason you think this patient should not continue in the study? (If yes, please explain in the Comments)	Yes ☐	No ☐
3. If the patient has an LV thrombus or atrial fibrillation, does either condition require current anticoagulation therapy?	Yes ☐	No ☐
4. Have there been any additional tests that have revealed evidence of LV thrombus that requires anticoagulation therapy?	Yes ☐	No ☐
Comments:		

RNC Signature_____ Date:_____

PI Signature_____ Date:_____

Entered to eCRF ☐ Initials _____

FORM NO. CNC005			
Acrostic Identifier:			
Study ID:			
Date source/workbook completed: ____/____/_____			

Physical Exam *(Day after Infusion)*

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

Review of Systems:

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

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

Telemetry

If intervention was required, select arrhythmia that required intervention (see list on page 2)	Describe intervention:
If intervention was required, select arrhythmia that required intervention (see list on page 2)	Describe intervention:
If intervention was required, select arrhythmia that required intervention (see list on page 2)	Describe intervention:

FORM NO. CNC005	
Acrostic Identifier:	
Study ID:	
Date source/workbook completed: ____/____/_____	

Physical Exam *(Day after Infusion)*	
Questions	
Has the patient experienced an adverse event since receiving study product? (If yes, complete AE form)	Yes ☐ No ☐
Have there been any changes to medications since receiving study product? (If yes, update medication form)	Yes ☐ No ☐
Have there been any ECG changes from baseline? (see ECG form)	Yes ☐ No ☐
If yes, are the changes clinically significant? (see ECG form)	Yes ☐ No ☐
Was the temperature log given to the patient?	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 cryostorage 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 ☐
Comments:	

Arrhythmias: *sinus tachycardia, atrial fibrillation/flutter, accelerated idioventricular rhythm, multifocal atrial tachycardia, supraventricular tachycardia, junctional tachycardia/rhythm, ventricular fibrillation*

Entered to eCRF ☐ Initials _____

FORM NO. CNC021			
Acrostic Identifier:			
Study ID:			
Date source/workbook completed: ____/____/_____			
Laboratory Tests (Day after Infusion)			
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 Enzymes (Either Troponin T or Troponin I should be completed, NOT both.)			
Troponin T (Time: __ __:__ __)		ng/ml	0.0-10 ng/ml
Troponin I (Time: __ __:__ __)		ng/ml	0.0-100 ng/ml
CK (Time: __ __:__ __)		U/L	25-10,000 U/L
CK-MB (Time: __ __:__ __)		ng/ml	0.0-250 ng/ml
Renal Panel	**Result**	**Unit**	**Normal Range**
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
Creatine		mg/dL	0.4-1.5 mg/dL
Albumin		g/dL	3.5-5.0 gm/dL
Calcium		mg/dL	8.0-10.6 mg/dL
Inorganic Phosphorus		mg/dL	2.5-4.7 mg/dL

FORM NO. CNC021			
Acrostic Identifier:			
Study ID:			
Date source/workbook completed: ____/____/_____			
Laboratory Tests (Day after Infusion)			
Hepatic Panel			
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
Comments:			

PI Signature_____ Date:_____

Entered to eCRF ☐ Initials _____

FORM NO. CNC024

Acrostic Identifier:

Study ID:

Date source/workbook completed: ____/____/_____

ECG *(Day after Infusion)*

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 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. CNC099 Screening/Demographics
2. CNC001 Eligibility
3. CNC003 Baseline Risk Factors & Other Cardiac History
4. CNC004 Baseline Non Cardiovascular Medical History
5. CNC011 Medication List*
6. CNC012 Medication Allergies*
7. CNC024 ECG (Baseline)
8. CNC006 Index Event (Revascularization)
9. CNC005 Baseline Physical Exam
10. CNC021 Baseline Laboratory Tests
11. CNC007 Treatment Checklist

*CNC011 and CNC012 are on the same page

_____ _____

Signature Date

_____

Printed Name

FORM COMPLETION ATTESTATION

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

1. CNC005 Day of Infusion Physical Exam
2. CNC029 Bone Marrow Aspiration
3. CNC031 Study Product Infusion

_____ _____

Signature Date

_____

Printed Name

FORM COMPLETION ATTESTATION

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

1. CNC005 Day after Infusion Physical Exam
2. CNC021 Day after Infusion Laboratory Tests
3. CNC024 ECG

_____ _____

Signature Date

_____

Printed Name

FORM COMPLETION ATTESTATION

All of the following forms associated with **Month 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. CNC005 Month 1 Physical Exam
2. CNC022 Month 1 Laboratory Tests
3. CNC024 ECG
4. CNC023 Holter

_____ _____

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. CNC005 Month 3 Physical Exam
2. CNC022 Month 3 Laboratory Tests

_____ _____

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. CNC005 Month 6 Physical Exam
2. CNC022 Month 6 Laboratory Tests
3. CNC024 ECG

_____ _____

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. CNC005 Month 12 Physical Exam
2. CNC022 Month 12 Laboratory Tests

_____ _____

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. CNC005 Month 24 Physical Exam
2. CNC022 Month 24 Laboratory Tests

_____ _____

Signature Date

_____

Printed Name

FORM NO. CNC005			
Acrostic Identifier:			
Study ID:			
Date source/workbook completed: ____/____/_____			
Physical Exam *(Month 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:**
Weight:	_____ pounds	☐ I
Temperature:	__ __.__°F ☐ oral ☐ auricle	☐ II
Respirations:	__ __ breaths/minute	☐ III
Heart rate:	__ __ __ beats/minute	☐ IV
Blood Pressure:	___ ___ ___ / ___ ___ ___ mmHg (supine) SBP DBP	☐ N/A

Review of Systems:

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

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

FORM NO. CNC005	
Acrostic Identifier:	
Study ID:	
Date source/workbook completed: ____/____/_____	

Physical Exam *(Month 1)*

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 changes to medications since the last follow-up visit? (If yes, update medication form)	Yes ☐ No ☐
Have there been any ECG changes from baseline? (see ECG form) If yes, are the changes clinically significant? (see ECG form)	Yes ☐ No ☐ Yes ☐ No ☐
Were there any significant findings on the Holter report? (see Holter form)	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 cryostorage drawn to ship to the biorepository? (If no, please explain in Comments) **Verify patient consented to Biorepository before you draw Biorepository bloods.**	Yes ☐ No ☐
Comments:	

Entered to eCRF ☐ Initials _____

FORM NO. CNC022			
Acrostic Identifier:			
Study ID:			
Date source/workbook completed: ____/____/_____			
Laboratory Tests *(Month 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%
Hepatic Panel			
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
Comments:			

PI Signature_____ Date:_____

Entered to eCRF ☐ Initials _____

FORM NO. CNC024

Acrostic Identifier:

Study ID:

Date source/workbook completed: ____/____/_____

ECG *(Month 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
- ☐ Right ventricular hypertrophy
- ☐ Left ventricular hypertrophy

FORM NO. CNC024

Acrostic Identifier:

Study ID:

Date source/workbook completed: ____/____/_____

ECG *(Month 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 R wave V_1, 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 ☐	/A ☐		
Are there nonspecific ST and/or T wave abnormalities present?	Y ☐	N ☐			

Comments:

PI Signature_____ Date:_____

Entered to eCRF ☐ Initials _____

FORM NO. CNC023

Acrostic Identifier:

Study ID:

Date source/workbook completed: _____/_____/_____

Holter Data Form *(Month 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. CNC005

Acrostic Identifier:

Study ID:

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

Review of Systems:

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

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

FORM NO. CNC005	
Acrostic Identifier:	
Study ID:	
Date form completed: _____/_____/_____	
Physical Exam *(Month 3)*	
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 changes to medications since the last follow-up visit? (If yes, update medication form)	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 cryostorage drawn to ship to the biorepository? (If no, please explain in Comments) **Verify patient consented to Biorepository before you draw Biorepository bloods.**	Yes ☐ No ☐
Comments:	

Entered to eCRF ☐ Initials _____

FORM NO. CNC022

Acrostic Identifier:

Study ID:

Date 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%
Hepatic Panel			
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

Comments:

PI Signature_____ Date:_____

Entered to eCRF ☐ Initials _____

FORM NO. CNC005

Acrostic Identifier:

Study ID:

Date source/workbook 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:
Weight:	_____ pounds	☐ I
Temperature:	_____°F ☐ oral ☐ auricle	☐ II
Respirations:	__ __ breaths/minute	☐ III
Heart rate:	__ __ __ beats/minute	☐ IV
Blood Pressure:	___ ___ ___ / ___ ___ ___ mmHg (supine) SBP DBP	☐ N/A

Review of Systems:

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

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

FORM NO. CNC005	
Acrostic Identifier:	
Study ID:	
Date source/workbook completed: ____/____/_____	
Physical Exam *(Month 6)*	
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 changes to medications since the last follow-up visit? (If yes, update Medication form)	Yes ☐ No ☐
Have there been any ECG changes from baseline? (see ECG form)	Yes ☐ No ☐
If yes, are the changes clinically significant? (see ECG form)	Yes ☐ No ☐
Was the Echo completed to send to the Core Lab? (If no, please enter a reason in Comments)	Yes ☐ No ☐
Was the MRI completed to send to the Core Lab? (If no, please enter a reason 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 cryostorage drawn to ship to the biorepository? (If no, please explain in Comments) **Verify patient consented to Biorepository before you draw Biorepository bloods.**	Yes ☐ No ☐
Comments:	

Entered to eCRF ☐ Initials _____

FORM NO. CNC022			
Acrostic Identifier:			
Study ID:			
Date source/workbook 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%
Hepatic Panel			
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
Comments:			

PI Signature_____ Date:_____

Entered to eCRF ☐ Initials _____

FORM NO. CNC024

Acrostic Identifier:

Study ID:

Date source/workbook 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
- ☐ Right ventricular hypertrophy
- ☐ Left ventricular hypertrophy

FORM NO. CNC024

Acrostic Identifier:

Study ID:

Date source/workbook 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_1, 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. CNC005

Acrostic Identifier:

Study ID:

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

Review of Systems:

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

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

FORM NO. CNC005	
Acrostic Identifier:	
Study ID:	
Date form completed: _____/_____/_____	
Physical Exam *(Month 12)*	
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 changes to medications since the last follow-up visit? (If yes, update Medication form)	Yes ☐ No ☐
Was the safety MRI completed? (If no, please explain in Comments)	Yes ☐ No ☐
Was the safety Echo completed? (The safety Echo is only required if the MRI is contraindicated) (If both safety MRI and safety Echo not done then a comment is required)	Yes ☐ No ☐
Comments:	

Entered to eCRF ☐ Initials _____

FORM NO. CNC022

Acrostic Identifier:

Study ID:

Date form completed: ____/____/____

Laboratory Tests *(Month 12)*

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%
Hepatic Panel			
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

Comments:

PI Signature_____ Date:_____

Entered to eCRF ☐ Initials _____

FORM NO. CNC005

Acrostic Identifier:

Study ID:

Date form completed: ____/____/____

Physical Exam *(Month 24)*

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

Review of Systems:

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

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

FORM NO. CNC005	
Acrostic Identifier:	
Study ID:	
Date form completed: _____/_____/_____	
Physical Exam *(Month 24)*	
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 changes to medications since the last follow-up visit? (If yes, update Medication form)	Yes ☐ No ☐
Was the safety MRI completed? (If no, please explain in Comments)	Yes ☐ No ☐
Was the safety Echo completed? (The safety Echo is only required if the MRI is contraindicated) (If both safety MRI and safety Echo not done then a comment is required)	Yes ☐ No ☐
Comments:	

Entered to eCRF ☐ Initials _____

FORM NO. CNC022

Acrostic Identifier:

Study ID:

Date form completed: ____/____/____

Laboratory Tests *(Month 24)*

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%
Hepatic Panel			
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

Comments:

PI Signature_____ Date:_____

Entered to eCRF ☐ Initials _____

FORM NO. CNC005			
Acrostic Identifier:			
Study ID:			
Date 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:**
Weight:	_____ pounds	☐ I
Temperature:	__ __.__°F ☐ oral ☐ auricle	☐ II
Respirations:	__ __ breaths/minute	☐ III
Heart rate:	__ __ __ beats/minute	☐ IV
Blood Pressure:	__ __ __ / __ __ __ mmHg (supine) SBP DBP	☐ N/A **LVEF: __ __ %**

Review of Systems:

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

Review of Systems	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 changes to medication since the last follow-up visit ? (If yes, update medication form)	Yes ☐ No ☐
Comments:	

Entered to eCRF ☐ Initials _____

FORM NO. CNC026

Acrostic Identifier:

Study ID:

Date form completed: ____/____/_____

Laboratory Tests (Interim)

Reason for Interim Lab:

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 Enzymes (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
Renal Panel			
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
Albumin		g/dL	3.5-5.0 gm/dL
Calcium		mg/dL	8.0-10.6 mg/dL
Inorganic Phosphorus		mg/dL	2.5-4.7 mg/dL

FORM NO. CNC026			
Acrostic Identifier:			
Study ID:			
Date form completed: ____/____/_____			
Laboratory Tests (Interim)			
Hepatic Panel	**Result**	**Unit**	**Normal Range**
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
Lipid Panel			
Cholesterol		mg/dL	100-240 mg/dL
Triglycerides		mg/dL	0-200 mg/dL
HDL Cholesterol		mg/dL	32-95 mg/dL
Calculated LDL		mg/dL	60-129 mg/dL
Chol / HDL Ratio			0-4.5
Other Tests			
BNP		pg/ml	0-100 pg/ml
hsCRP		mg/L	0.0-40 mg/L
Pregnancy Test (women of childbearing age) ☐ Not applicable age or gender			Negative (urine) < 5.0 mU/ml (quantitative blood)
Comments:			

PI Signature_____ Date:_____

Entered to eCRF ☐ Initials _____

FORM NO. CNC041

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

☐ Investigator reviewed and signed AE report

Date Investigator reviewed: ____/____/_____

RNC Signature_____ Date:_____

Entered to eCRF ☐ Initials _____

FORM NO. CNC042

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

☐ Investigator reviewed and signed SAE report

Date Investigator reviewed: ____/____/_____

Entered to eCRF ☐ Initials _____

FORM NO. CNC043

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

Entered to eCRF ☐ Initials _____

FORM NO. CNC044		
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. CNC048			
Acrostic Identifier:			
Study ID:			
Missing Form			
Form Missing:		**Reason/Comment:**	**Date of this Entry:**
☐	BSL Risk Factors & Other Cardiac Hx		
☐	BSL Non Cardio. Med. Hx		
☐	BSL - Physical Exam		
☐	BSL - ECG		
☐	BSL - Labs		
☐	Medication allergies		
☐	Medication list		
☐	Index Event (Revascularization)		
☐	Bone Marrow Aspiration		
☐	Study Product Infusion		
☐	Day of Infusion - Phys. Exam		
☐	Day after Infusion - Phys. Exam		
☐	Day after Infusion - ECG		
☐	Day after Infusion - Labs		
☐	Mo 1 - Physical Exam		
☐	Mo 1 - Labs (F/U)		
☐	Mo 1 - ECG		
☐	Holter		
☐	Mo 3 - Physical Exam		
☐	Mo 3 - Labs (F/U)		
☐	Mo 6 - Physical Exam		
☐	Mo 6 - Labs (F/U)		
☐	Mo 6 - ECG		
☐	Mo 12 - Physical Exam		
☐	Mo 12 - Labs (F/U)		
☐	Mo 24 - Physical Exam		
☐	Mo 24 - Labs (F/U)		
☐	End of Study		

FORM NO. CNC051

Acrostic Identifier:

Study ID:

Date form completed: ____/____/_____

End of Study

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

Reason for discharge from the study:

- ☐ Completed study — Date of Discharge from Study: ____/____/_____
- ☐ Withdrawn — Date of Discharge from Study: ____/____/_____
- ☐ Lost to follow-up — Date of Discharge from Study: ____/____/_____
- ☐ Screen Failure — Date of Discharge from Study: ____/____/_____

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:_____

RNC Signature_____ Date:_____

Entered to eCRF ☐ Initials _____