



# Cardiovascular Cell Therapy Research Network

TIME Protocol Workbook

<b>FORM NO. CNB005</b>				
Acrostic Identifier:				
Study ID:				
Date form completed: ____ / ____ / ____				
<b>Physical Exam (Day of Infusion - 3 Day Group)</b>				
Date of Exam: ____ / ____ / ____		<input type="checkbox"/> Visit is outside time window		Reason:
<b>Vital Signs</b>			<b>NYHA Class:</b>	
Weight:	_____ pounds			<input type="checkbox"/> I
Temperature:	_____°F <input type="checkbox"/> oral <input type="checkbox"/> auricle			<input type="checkbox"/> II
Respirations:	___ breaths/minute			<input type="checkbox"/> III
Heart rate:	___ beats/minute			<input type="checkbox"/> IV
Blood Pressure:	___ / ___ mmHg (supine)			<input type="checkbox"/> N/A
		SBP	DBP	
<b>Review of Systems:</b>				
Have changes occurred since previous visit? Yes <input type="checkbox"/> No <input type="checkbox"/> If no, the table is complete.				
<u>Review of Systems</u>	<u>Normal</u>	<u>Abnormal</u>	<u>Not Examined</u>	<u>Describe</u>
Skin	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
HEENT	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Lungs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
CV	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Abdomen	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Lymph Nodes	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Musculoskeletal	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Neurological	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Other: _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Questions:</b>				
Has the patient experienced any adverse events? (If yes, complete AE form)		Yes <input type="checkbox"/> No <input type="checkbox"/>		
Have there been any changes to medications? (If yes, update medication form)		Yes <input type="checkbox"/> No <input type="checkbox"/>		
Was the "Day 3" MRI completed and results sent to the Core Lab? (If no, please explain in the Comments)		Yes <input type="checkbox"/> No <input type="checkbox"/>		
Were five 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)		Yes <input type="checkbox"/> No <input type="checkbox"/>		
<b>Verify patient consented to Biorepository before you draw Biorepository bloods.</b>				
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 Comments)		Yes <input type="checkbox"/> No <input type="checkbox"/>		
Comments:				

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**Cardiovascular Cell Therapy Research Network**  
TIME Protocol Workbook

<b>FORM NO. CNB005</b>				
Acrostic Identifier:				
Study ID:				
Date form completed: ____ / ____ / ____				
<b>Physical Exam (Day of Infusion - 7 Day Group)</b>				
Date of Exam: ____ / ____ / ____		<input type="checkbox"/> Visit is outside time window		Reason:
<b>Vital Signs</b>			<b>NYHA Class:</b>	
Weight:	_____ pounds		<input type="checkbox"/> I	
Temperature:	_____°F <input type="checkbox"/> oral <input type="checkbox"/> auricle		<input type="checkbox"/> II	
Respirations:	___ breaths/minute		<input type="checkbox"/> III	
Heart rate:	___ beats/minute		<input type="checkbox"/> IV	
Blood Pressure:	___ / ___ mmHg (supine) SBP                  DBP		<input type="checkbox"/> N/A	
<b>Review of Systems:</b>				
Have changes occurred since previous visit?    Yes <input type="checkbox"/> No <input type="checkbox"/> If no, the table is complete.				
<u>Review of Systems</u>	<u>Normal</u>	<u>Abnormal</u>	<u>Not Examined</u>	<u>Describe</u>
Skin	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
HEENT	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Lungs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
CV	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Abdomen	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Lymph Nodes	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Musculoskeletal	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Neurological	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Other: _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Questions:</b>				
Has the patient experienced any adverse events? (If yes, complete AE form)			Yes <input type="checkbox"/> No <input type="checkbox"/>	
Have there been any changes to medications? (If yes, update medication form)			Yes <input type="checkbox"/> No <input type="checkbox"/>	
Was the "Day 3" MRI completed and results sent to the Core Lab? (If no, please explain in the Comments)			Yes <input type="checkbox"/> No <input type="checkbox"/>	
Were five 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)			Yes <input type="checkbox"/> No <input type="checkbox"/>	
<b>Verify patient consented to Biorepository before you draw Biorepository bloods.</b>				
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 Comments)			Yes <input type="checkbox"/> No <input type="checkbox"/>	
Comments:				

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# Cardiovascular Cell Therapy Research Network

TIME Protocol Workbook

FORM NO. CNB029	
Acrostic Identifier:	
Study ID:	
Date form completed: ____ / ____ / ____	
<b>Bone Marrow Aspiration</b>	
Procedure Date:	____ / ____ / ____
Procedure Venue:	<input type="checkbox"/> Patient Room <input type="checkbox"/> Cath Lab <input type="checkbox"/> 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 <input type="checkbox"/> No <input type="checkbox"/>
Were concomitant medications given? (If yes, add to Medication form)	Yes <input type="checkbox"/> No <input type="checkbox"/>
Comments:	

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Initials \_\_\_\_\_



FORM NO. CNB031			
Acrostic Identifier:			
Study ID:			
Date form completed: ___ / ___ / ___			
<b>Vital Signs Pre-Cath (Pre-Study Product Infusion)</b>			
Date: ___ / ___ / ___ Time: ___:___			
Temperature:	_____°F	<input type="checkbox"/> oral	<input type="checkbox"/> auricle
Respirations:	___ breaths/minute		
Heart rate:	___ beats/minute		
Blood Pressure:	___ / ___	mmHg (supine)	
	SBP	DBP	
<b>Study Product Infusion Period</b>			
Procedure	Start Date: ___/___/___	Start Time: ___:___	
	Stop Date: ___/___/___	Stop Time: ___:___	
Was the revascularized vessel patent at the time of cell administration?	No <input type="checkbox"/>	Yes <input type="checkbox"/>	If no, pt is ineligible for continuation; fill out an AE and End of Study form
ST segment changes?	No <input type="checkbox"/>	Yes <input type="checkbox"/>	
Nitroglycerin given?	No <input type="checkbox"/>	Yes <input type="checkbox"/>	Amount: ___ mcg (IC)
Heparin given?	No <input type="checkbox"/>	Yes <input type="checkbox"/>	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: ___:___	<input type="checkbox"/> Not done
Infusion 2	Start Date: ___/___/___	Start Time: ___:___	Volume of infusion 2: ___ ml
	Stop Date: ___/___/___	Stop Time: ___:___	<input type="checkbox"/> Not done
Infusion 3	Start Date: ___/___/___	Start Time: ___:___	Volume of infusion 3: ___ ml
	Stop Date: ___/___/___	Stop Time: ___:___	<input type="checkbox"/> Not done
Infusion 4	Start Date: ___/___/___	Start Time: ___:___	Volume of infusion 4: ___ ml
	Stop Date: ___/___/___	Stop Time: ___:___	<input type="checkbox"/> Not done
Infusion 5	Start Date: ___/___/___	Start Time: ___:___	Volume of infusion 5: ___ ml
	Stop Date: ___/___/___	Stop Time: ___:___	<input type="checkbox"/> Not done
Infusion 6	Start Date: ___/___/___	Start Time: ___:___	Volume of infusion 6: ___ ml
	Stop Date: ___/___/___	Stop Time: ___:___	<input type="checkbox"/> Not done



# Cardiovascular Cell Therapy Research Network

TIME Protocol Workbook

FORM NO. CNB031	
Acrostic Identifier:	
Study ID:	
Date form completed: ____ / ____ / ____	
<b>Vital Signs Post-Cath (Post-Study Product Infusion)</b>	
Date: ____ / ____ / ____ Time: __ __: __ __	
Temperature:	_____°F <input type="checkbox"/> oral <input type="checkbox"/> auricle
Respirations:	__ __ breaths/minute
Heart rate:	__ __ __ beats/minute
Blood Pressure:	__ __ __ / __ __ __ mmHg (supine) SBP                  DBP
<b>Questions</b>	
1. Was the procedure prematurely stopped? (If yes, complete AE or SAE, and/or UP form)	Yes <input type="checkbox"/> No <input type="checkbox"/>
2. Was the procedure restarted?	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
3. Did the patient experience an adverse event during the procedure? (If yes, complete AE or SAE form)	Yes <input type="checkbox"/> No <input type="checkbox"/>
4. Were concomitant medications given? (If yes, add to Medication form)	Yes <input type="checkbox"/> No <input type="checkbox"/>
Comments:	

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# Cardiovascular Cell Therapy Research Network

## TIME Protocol Workbook

<b>FORM #</b>	<b>DESCRIPTION of TIME FORMS</b>	<b>TIME Excel Wkbk tab name</b>
CNB099	Screening/Demographics	Enrollmt
CNB001	Eligibility	Elig
CNB003	Baseline Risk Factors & Other Cardiac Hx	Risk
CNB004	Baseline Non Cardio. Med. Hx	Med Hx
CNB005	Physical Exams	BSL PE/PE
CNB006	Index Event (Revascularization)	PCI
CNB007	Treatment Checklist	Treatment
CNB011	Medication List	Meds
CNB012	Medication Allergies	Meds
CNB021	Labs (Panels)	BSL Labs/D1 Labs
CNB022	Labs (F/U)	Labs M 6,12,24
CNB023	Holter	Holter
CNB024	ECG	ECG
CNB026	Labs (Interim)	Interim Labs
CNB029	Bone Marrow Aspiration	Aspir
CNB031	Study Product Infusion	SPI
CNB041	Adverse Event	AE
CNB042	Serious Adverse Event	SAE
CNB043	Unanticipated Problem	UP
CNB044	Protocol Deviation	Prot Dev
CNB045	Schedule of Procedures	Sched
CNB047	Data Glossary	Glossary
CNB048	Missing Form	Missing
CNB051	End of Study	End



# Cardiovascular Cell Therapy Research Network

## TIME Protocol Workbook

FORM NO. CNB045	
Acrostic Identifier:	
Study ID:	
<b>Schedule of Procedures TIME 3-Day Group</b>	
Procedures	Time Window
<b>Screening/Baseline</b>	
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 EKG Baseline Echo (core) Treatment Checklist	
<b>Aspiration/Infusion (SPI)</b>	
Day of Infusion PE Biorepository blood draws (if consented) Bone Marrow Aspiration Baseline cMRI (core) Cell Processing Cell Processing - Post Release Study Product Infusion	<b>MI + 3 days +/- 1 day</b>
<b>Day after Infusion</b>	
Day after Infusion PE Biorepository blood draws (if consented) Day after Infusion Lab Panels Day after Infusion EKG	<b>SPI + 1</b>
<b>1 Month</b>	
PE Labs (F/U) Biorepository blood draws (if consented) EKG Holter	<b>SPI + 30 days +/- 7 days</b>
<b>3 Month</b>	
PE Labs (F/U) Biorepository blood draws (if consented)	<b>SPI + 90 days +/- 14 days</b>
<b>6 Month</b>	
PE Labs (F/U) EKG Biorepository blood draws (if consented) Echo (core) cMRI (core)	<b>SPI + 180 days +/- 30 days</b>



# Cardiovascular Cell Therapy Research Network

## TIME Protocol Workbook

FORM NO. CNB045	
Acrostic Identifier:	
Study ID:	
<b>Schedule of Procedures TIME 3-Day Group</b>	
Procedures	Time Window
<b>12 Month</b>	<b>SPI + 365 days +/- 30 days</b>
PE Labs (F/U) cMRI*	
<b>24 Month</b>	<b>SPI + 730 days +/- 30 days</b>
PE Labs (F/U) cMRI* End of Study	

\*echo at 12 & 24 months if cMRI is contraindicated

cMRI: all pts. undergo cMRI at Day 3 and pts. Rz to therapy Day 7 undergo repeat cMRI on Day 7 (Day 3 MRI=baseline)

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 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 infusion]

Mo 1,3: CBC/diff, hepatic panel

Mo 6,12,24: CBC/diff, hepatic panel, & BNP





# Cardiovascular Cell Therapy Research Network

## TIME Protocol Workbook

FORM NO. CNB045	
Acrostic Identifier:	
Study ID:	
<b>Schedule of Procedures TIME 7-Day Group</b>	
Procedures	Time Window
<b>Screening/Baseline</b>	
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 EKG Baseline Echo (core) Treatment Checklist	
<b>Day 3</b>	<b>MI + 3 days +/- 1 day</b>
Baseline cMRI (core)	
<b>Aspiration/Infusion (SPI)</b>	
Day of Infusion PE Biorepository blood draws (if consented) Bone Marrow Aspiration cMRI Cell Processing Cell Processing - Post Release Study Product Infusion	
<b>Day after Infusion</b>	<b>SPI + 1</b>
Day after Infusion PE Biorepository blood draws (if consented) Day after Infusion Lab Panels Day after Infusion EKG	
<b>1 Month</b>	<b>SPI + 30 days +/- 7 days</b>
PE Labs (F/U) Biorepository blood draws (if consented) EKG Holter	
<b>3 Month</b>	<b>SPI + 90 days +/- 14 days</b>
PE Labs (F/U) Biorepository blood draws (if consented)	
<b>6 Month</b>	<b>SPI + 180 days +/- 30 days</b>
PE Labs (F/U) EKG Biorepository blood draws (if consented) Echo (core) cMRI (core)	



**Cardiovascular Cell Therapy Research Network**  
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FORM NO. CNB045	
Acrostic Identifier:	
Study ID:	
<b>Schedule of Procedures TIME 7-Day Group</b>	
<b>Procedures</b>	<b>Time Window</b>
<b>12 Month</b>	<b>SPI + 365 days +/- 30 days</b>
PE Labs (F/U) cMRI*	
<b>24 Month</b>	<b>SPI + 730 days +/- 30 days</b>
PE Labs (F/U) cMRI* End of Study	

\*echo at 12 & 24 months if cMRI is contraindicated

cMRI: all pts. undergo cMRI at Day 3 and pts. Rz to therapy Day 7 undergo repeat cMRI on Day 7 (Day 3 MRI=baseline)

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 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 infusion]

Mo 1,3: CBC/diff, hepatic panel

Mo 6,12,24: CBC/diff, hepatic panel, & BNP



# Cardiovascular Cell Therapy Research Network

TIME Protocol Workbook

FORM NO. CNB099		
Date source/workbook completed: ____/____/____		
<b>Screening / Demographics</b>		
Last Name:		
First Name:		
Middle Initial:		
Consent signed <input type="checkbox"/>	Biorepository consent signed	<input type="checkbox"/> Yes <input type="checkbox"/> No
Date of Birth	____/____/____	
Sex	M <input type="checkbox"/> F <input type="checkbox"/>	
Hispanic	N <input type="checkbox"/> Y <input type="checkbox"/>	
Race (choose one):		
White		<input type="checkbox"/>
Black or African American		<input type="checkbox"/>
Asian		<input type="checkbox"/>
Native Hawaiian or Other Pacific Islander		<input type="checkbox"/>
American Indian or Alaska Native		<input type="checkbox"/>
Other		<input type="checkbox"/>
Marital Status (choose one):		
Married		<input type="checkbox"/>
Living with a partner		<input type="checkbox"/>
Single/never married		<input type="checkbox"/>
Widowed		<input type="checkbox"/>
Divorced		<input type="checkbox"/>
Separated		<input type="checkbox"/>

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# Cardiovascular Cell Therapy Research Network

TIME Protocol Workbook

FORM NO. CNB001		
Acrostic Identifier:		
Study ID:		
Date source/workbook completed: ___ / ___ / _____		Date of PCI: ___ / ___ / _____
<b>Eligibility Criteria</b>		
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.		
<b>Y</b>	<b>N</b>	<b>Inclusion Criteria (Must answer Yes to all questions to be eligible)</b>
<input type="checkbox"/>	<input type="checkbox"/>	Patient is at least 21 years of age
<input type="checkbox"/>	<input type="checkbox"/>	First MI with successful primary PCI in an artery diameter $\geq 2.5$ mm within 24 hours of onset of symptoms
<input type="checkbox"/>	<input type="checkbox"/>	No contraindications to undergoing cell therapy procedure within 3-7 days post AMI and PCI
<input type="checkbox"/>	<input type="checkbox"/>	Hemodynamic stability as defined as not requiring IABP, inotropic or blood pressure supporting medications
<input type="checkbox"/>	<input type="checkbox"/>	Ejection fraction following reperfusion with PCI $\leq 45\%$ as assessed by echocardiography
<input type="checkbox"/>	<input type="checkbox"/>	Consent signed. Date signed ___ / ___ / _____
<input type="checkbox"/>	<input type="checkbox"/>	Women of childbearing potential willing to use an active form of birth control (If male, check "Y")
<b>Y</b>	<b>N</b>	<b>Exclusion Criteria (Must answer No to all questions to be eligible)</b>
<input type="checkbox"/>	<input type="checkbox"/>	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)
<input type="checkbox"/>	<input type="checkbox"/>	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)
<input type="checkbox"/>	<input type="checkbox"/>	History of any malignancy within the past 5 years excluding non-melanoma skin cancer or cervical cancer <i>in-situ</i>
<input type="checkbox"/>	<input type="checkbox"/>	History of chronic anemia (hemoglobin (Hgb) $< 9.0$ mg/dl)
<input type="checkbox"/>	<input type="checkbox"/>	History of thrombocytosis (platelets $> 500k$ )
<input type="checkbox"/>	<input type="checkbox"/>	Baseline platelet count (prior to revascularization) $< 120,000$ or known history of thrombocytopenia
<input type="checkbox"/>	<input type="checkbox"/>	Known history of elevated INR (PT) or PTT
<input type="checkbox"/>	<input type="checkbox"/>	Life expectancy less than one year
<input type="checkbox"/>	<input type="checkbox"/>	History of untreated alcohol or drug abuse
<input type="checkbox"/>	<input type="checkbox"/>	Currently enrolled in another investigational drug or device trial
<input type="checkbox"/>	<input type="checkbox"/>	Previous CABG
<input type="checkbox"/>	<input type="checkbox"/>	Previous MI with resultant LVEF $< 55\%$
<input type="checkbox"/>	<input type="checkbox"/>	History of stroke or TIA within the past 6 months
<input type="checkbox"/>	<input type="checkbox"/>	History of severe valvular heart disease (aortic valve area $< 1.0$ cm <sup>2</sup> or $> 3+$ mitral regurgitation)



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FORM NO. CNB001

Acrostic Identifier:

Study ID:

### Eligibility Criteria

Y	N	Exclusion Criteria continued (Must answer No to all questions to be eligible)
<input type="checkbox"/>	<input type="checkbox"/>	Pregnant or breast feeding
<input type="checkbox"/>	<input type="checkbox"/>	Has a known history of HIV, or has active Hepatitis B or C infection, or active TB
<input type="checkbox"/>	<input type="checkbox"/>	Has an active inflammatory or autoimmune disease on chronic immunosuppressive therapy
<input type="checkbox"/>	<input type="checkbox"/>	Contraindications to cMRI
<input type="checkbox"/>	<input type="checkbox"/>	Previous radiation to the pelvis with WBC and platelet counts below hospital-specific normal values
<input type="checkbox"/>	<input type="checkbox"/>	Women of childbearing potential not willing to use an active form of birth control (If male, check "N")
<input type="checkbox"/>	<input type="checkbox"/>	Chronic liver disease that might interfere with survival or treatment with cell therapy
<input type="checkbox"/>	<input type="checkbox"/>	Chronic renal insufficiency as defined by a creatinine $\geq$ 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 CCTR 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)

Comments:

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

RNC Signature \_\_\_\_\_ Date: \_\_\_\_\_

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**Cardiovascular Cell Therapy Research Network**  
TIME Protocol Workbook

FORM NO. CNB003			
Acrostic Identifier:			
Study ID:			
Date source/workbook completed: ____ / ____ / ____			
<b>Baseline Risk Factors</b>			
<b>Diabetes</b>	No <input type="checkbox"/>	Type I <input type="checkbox"/>	Type II <input type="checkbox"/>
<u>Diabetes Treatment:</u>	Oral Hypoglycemics <input type="checkbox"/>	Insulin <input type="checkbox"/>	
	Neither <input type="checkbox"/>		
<b>Hypertension</b>	No <input type="checkbox"/>	Yes <input type="checkbox"/>	
<u>Hypertension Treatment:</u>		1 med <input type="checkbox"/>	
		2 or more meds <input type="checkbox"/>	
		no medication <input type="checkbox"/>	
<b>Hyperlipidemia</b>	No <input type="checkbox"/>	Yes <input type="checkbox"/>	
<u>Hyperlipidemia Treatment:</u>		Diet controlled <input type="checkbox"/>	
		Drug controlled <input type="checkbox"/>	
		Neither <input type="checkbox"/>	
<b>Family Hx of MI</b>	No <input type="checkbox"/>	Yes <input type="checkbox"/>	Unknown <input type="checkbox"/>
<b>Angina</b>	No <input type="checkbox"/>	Stable <input type="checkbox"/>	Unstable <input type="checkbox"/>
<b>Carotid Disease, asymptomatic</b>	No <input type="checkbox"/>	Yes <input type="checkbox"/>	
<b>Hx of TIAs</b>	No <input type="checkbox"/>	Yes <input type="checkbox"/>	
<b>Hx of valvular heart disease</b>	No <input type="checkbox"/>	Yes <input type="checkbox"/>	
<u>If yes, check all that apply:</u>		mitral <input type="checkbox"/>	
		aortic <input type="checkbox"/>	
		pulmonic <input type="checkbox"/>	
		tricuspid <input type="checkbox"/>	
<b>Hx of aneurysm</b>	No <input type="checkbox"/>	Yes <input type="checkbox"/>	
<b>Hx of Stroke</b>	No <input type="checkbox"/>	current deficit <input type="checkbox"/>	
<b>Hx of PVD</b>	No <input type="checkbox"/>	Yes <input type="checkbox"/>	
<b>Obese or Hx of obesity</b>	No <input type="checkbox"/>	Yes <input type="checkbox"/>	
<b>Smoking</b>	Never <input type="checkbox"/>	Previous <input type="checkbox"/>	Current <input type="checkbox"/>
		Yr stopped: _____	packs/day: _____



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FORM NO. CNB003					
Acrostic Identifier:					
Study ID:					
Date source/workbook completed: ___ / ___ / _____					
<b>Baseline Risk Factors</b>					
<b>Other Cardiac History</b>					
Prior to this hospitalization, have you been hospitalized for:					If yes, Date of most recent
Congestive Heart Failure	No	<input type="checkbox"/>	Yes	<input type="checkbox"/>	___ / ___ / ___
Revascularizations (non-CABG)	No	<input type="checkbox"/>	Yes	<input type="checkbox"/>	___ / ___ / ___
Previous MI	No	<input type="checkbox"/>	Yes	<input type="checkbox"/>	___ / ___ / ___
Bypass surgery (CABG)	No	<input type="checkbox"/>	Yes	<input type="checkbox"/>	___ / ___ / ___
Cardiac catheterization	No	<input type="checkbox"/>	Yes	<input type="checkbox"/>	___ / ___ / ___
Cardiac pacemaker	No	<input type="checkbox"/>	Yes	<input type="checkbox"/>	___ / ___ / ___
Other coronary interventions	No	<input type="checkbox"/>	Yes	<input type="checkbox"/>	
If yes, please describe other coronary interventions:					
<b>Procedure:</b>					<b>Date most recent:</b>
1.					___ / ___ / ___
2.					___ / ___ / ___
3.					___ / ___ / ___
Comments:					

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**Cardiovascular Cell Therapy Research Network**  
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FORM NO. CNB004

Acrostic Identifier:

Study ID:

Date source/workbook completed: \_\_\_\_/\_\_\_\_/\_\_\_\_

**Baseline Non-Cardiovascular Medical History**

<b>System</b>	<b>Not discussed</b>	<b>Unremarkable</b>	<b>Abnormal</b>	<b>Describe the abnormality (obligatory if abnormal)</b>
Ears, Nose, Throat	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Ophthalmic	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Respiratory	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
GI	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Renal	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Urogenital	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Neurologic	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Endocrine	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Musculoskeletal	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Skin	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Psychiatric	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Other	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Entered to eCRF

Initials \_\_\_\_\_





<b>FORM NO. CNB012</b>			
Acrostic Identifier:			
Study ID:			
Date source/workbook completed: ____/____/____			
<b>Medication Allergies</b>			
Drug Allergies	NKDA <input type="checkbox"/>	Yes <input type="checkbox"/>	Please list:

<b>FORM NO. CNB011</b>									
Acrostic Identifier:									
Study ID:									
Date form completed: ____ / ____ / ____									
<b>Medications</b>									
#	Medication Class	Medication Name	Dose	Unit	Frequency	Prior to Study Start	Start Date	Stop Date	Comments
1						<input type="checkbox"/>			
2						<input type="checkbox"/>			
3						<input type="checkbox"/>			
4						<input type="checkbox"/>			
5						<input type="checkbox"/>			
6						<input type="checkbox"/>			
7						<input type="checkbox"/>			
8						<input type="checkbox"/>			
9						<input type="checkbox"/>			
10						<input type="checkbox"/>			
11						<input type="checkbox"/>			
12						<input type="checkbox"/>			
13						<input type="checkbox"/>			
14						<input type="checkbox"/>			
15						<input type="checkbox"/>			
16						<input type="checkbox"/>			
17						<input type="checkbox"/>			
18						<input type="checkbox"/>			

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



*Medication eCRF drop down lists:*

<u>Drug Classes</u>	<u>Units</u>	<u>Frequency</u>
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. CNB024

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: (Choose 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 tachycardia (< 30 seconds) > 120 bpm (must fill in a & b if this box is checked)
- 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

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):

- AV block, 1st degree
- AV block, 2nd degree Mobitz type 1 (Wenkebach)
- AV block, 2nd degree Mobitz type 2
- AV block, 3rd degree

NONE

Abnormalities of P wave: (Choose all that apply)

- Left atrial enlargement
- Right atrial enlargement

NONE

Abnormalities of QRS axis (Choose one):

- Left axis deviation (> -30°)
- Right axis deviation (> +100°)

NONE

QRS voltage abnormalities: (Choose all that apply)

- Low voltage
- Left ventricular hypertrophy
- Right ventricular hypertrophy

NONE



**Cardiovascular Cell Therapy Research Network**  
TIME Protocol Workbook

<b>FORM NO. CNB024</b>					
Acrostic Identifier:					
Study ID:					
Date source/workbook completed: ____/____/____					
<b>ECG - Baseline</b>					
<b>Intraventricular conduction abnormalities: (Choose all that apply)</b>					<input type="checkbox"/> <b>NONE</b>
<input type="checkbox"/> Right bundle branch block, complete			<input type="checkbox"/> Left bundle branch block, complete		
<input type="checkbox"/> Right bundle branch block, incomplete			<input type="checkbox"/> Left bundle branch block, incomplete		
<input type="checkbox"/> Left anterior fascicular block			<input type="checkbox"/> Nonspecific intraventricular conduction disturbance		
<input type="checkbox"/> Left posterior fascicular block					
For each "Yes" response, check all locations that apply:					
Are Q waves present?	Y <input type="checkbox"/>	N <input type="checkbox"/>	Anterior <input type="checkbox"/>	Lateral <input type="checkbox"/>	Inferior <input type="checkbox"/>
Is ST segment elevation present?	Y <input type="checkbox"/>	N <input type="checkbox"/>	Anterior <input type="checkbox"/>	Lateral <input type="checkbox"/>	Inferior <input type="checkbox"/>
Is ST segment depression present?	Y <input type="checkbox"/>	N <input type="checkbox"/>	Anterior <input type="checkbox"/>	Lateral <input type="checkbox"/>	Inferior <input type="checkbox"/>
Is T wave inversion present?	Y <input type="checkbox"/>	N <input type="checkbox"/>	Anterior <input type="checkbox"/>	Lateral <input type="checkbox"/>	Inferior <input type="checkbox"/>
Is there evidence of posterior infarction?	Y <input type="checkbox"/>	N <input type="checkbox"/>	Pathologic R wave V <sub>1</sub> , V <sub>2</sub> <input type="checkbox"/>	Abn. ST depression V <sub>1</sub> , V <sub>2</sub> <input type="checkbox"/>	Abn. ST elevation V <sub>1</sub> , V <sub>2</sub> <input type="checkbox"/>
Is there evidence of RV infarction (right precordial leads)?	Y <input type="checkbox"/>	N <input type="checkbox"/>	N/A <input type="checkbox"/>		
Are there nonspecific ST and/or T wave abnormalities present?	Y <input type="checkbox"/>	N <input type="checkbox"/>			
Comments:					

PI Signature \_\_\_\_\_

Date: \_\_\_\_\_

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**Cardiovascular Cell Therapy Research Network**  
TIME Protocol Workbook

FORM NO. CNB006					
Acrostic Identifier:					
Study ID:					
Date source/workbook completed: ____/____/____					
<b>Revascularization / PCI</b>					
Date of onset of chest pain:	____/____/____	Time: ____:____			
Date patient presented at ER:	____/____/____	Time: ____:____			
Date of PCI:	____/____/____	Time: ____:____			
Calculated ischemic period:	<i>(program calculates time between onset of chest pain and PCI)</i>				
Calculated door-to-ballon time:	<i>(program calculates time between presented at ER and PCI)</i>				
TIMI Flow & TMP scores	Pre PCI: _____		Post PCI: _____		
<b>Artery Location of PCI</b> (Select all that apply)			<b>Stent Type</b>		
<b>Artery:</b>	<u>No</u>	<u>Yes</u>	<u>None</u>	<u>Drug eluting</u>	<u>Bare metal</u>
Circumflex	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
RCA	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
LAD	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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 <input type="checkbox"/>		Initials _____			



**Cardiovascular Cell Therapy Research Network**  
TIME Protocol Workbook

FORM NO. CNB005				
Acrostic Identifier:				
Study ID:				
Date source/workbook completed: ___/___/___				
<b>Physical Exam (Baseline)</b>				
Date of Exam: ___/___/___		<input type="checkbox"/> Visit is outside time window		Reason:
<b>Vital Signs</b>			<b>NYHA Class:</b>	
Height:	_____ inches		<input type="checkbox"/>	I
Weight:	_____ pounds		<input type="checkbox"/>	II
Temperature:	____.____°F <input type="checkbox"/> oral <input type="checkbox"/> auricle		<input type="checkbox"/>	III
Respirations:	____ breaths/min		<input type="checkbox"/>	IV
Heart rate:	____ beats/min		<input type="checkbox"/>	N/A
Blood Pressure:	_____ / _____ mmHg (supine)		LVEF: ____ % (screening echo)	
	SBP	DBP	Was there evidence of LV thrombus on the screening echo? <input type="checkbox"/> Yes <input type="checkbox"/> No	
<b>Review of Systems:</b>				
<u>Organs</u>	<u>Normal</u>	<u>Abnormal</u>	<u>Not Examined</u>	<u>Describe (must describe if answer abnormal)</u>
Skin	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
HEENT	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Lungs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
CV	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Abdomen	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Lymph Nodes	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Musculoskeletal	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Neurological	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Other: _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Questions</b>				
Has the patient experienced any adverse events? (If yes, complete AE form)		Yes <input type="checkbox"/> No <input type="checkbox"/>		
Was the baseline echo completed to send to the Core Lab? (If no, please enter a reason in Comments)		Yes <input type="checkbox"/> No <input type="checkbox"/>		
Comments:				

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



**Cardiovascular Cell Therapy Research Network**  
TIME Protocol Workbook

<b>FORM NO. CNB021</b>			
Acrostic Identifier:			
Study ID:			
Date source/workbook completed: ___/___/_____			
<b>Laboratory Tests (Baseline)</b>			
<b>Date and time specimen obtained: Date: ___/___/___ Time: ___:___</b>			
<b>CBC with Differential</b>	<b>Result</b>	<b>Unit</b>	<b>Normal Range</b>
WBC		K/mm <sup>3</sup>	4.0-11.0 K/mm <sup>3</sup>
RBC		M/mm <sup>3</sup>	4.0-6.0 M/mm <sup>3</sup>
Hgb		gm/dL	12.0-17.5 gm/dL
Hct		%	33-53%
MCV		fL	78-100 fL
Platelets		K/mm <sup>3</sup>	135-450 K/mm <sup>3</sup>
<b>WBC Differential</b>			
Neutrophils		%	36-74%
Lymphocytes		%	12-45%
Monocytes		%	0-13%
Eosinophils		%	0-8%
Basophils		%	< 3.0%
<b>Cardiac Enzymes (Either Troponin T or Troponin I should be completed, NOT both.)</b>			
Troponin T		ng/ml	0.0-10 ng/ml
Troponin I		ng/ml	0.0-100 ng/ml
CK		U/L	25-10,000 U/L
CK-MB		ng/ml	0.0-250 ng/ml
<b>Renal Panel</b>			
Na+		mmol/L	132-148 mmol/L
K+		mmol/L	3.3-5.5 mmol/L
Chloride		mmol/L	95-110 mmol/L
CO <sub>2</sub>		mmol/L	22-32 mmol/L
Glucose		mg/dL	65-110 mg/dL
BUN		mg/dL	5-26 mg/dL
Creatinine		mg/dL	0.4-1.5 mg/dL
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



**Cardiovascular Cell Therapy Research Network**  
TIME Protocol Workbook

<b>FORM NO. CNB021</b>			
Acrostic Identifier:			
Study ID:			
Date source/workbook completed: ____ / ____ / _____			
<b>Laboratory Tests (Baseline)</b>			
<b>Hepatic Panel</b>	<b>Result</b>	<b>Unit</b>	<b>Normal Range</b>
Bilirubin-Total		mg/dL	0.0-1.5 mg/dL
Bilirubin-Direct		mg/dL	0.0-0.4 mg/dL
Total Protein		g/dL	6.0-8.5 g/dL
Alk Phos		U/L	30-150 U/L
ALT		U/L	0-50 U/L
AST		U/L	0-42 U/L
<b>Lipid Panel</b>			
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
<b>Other Tests</b>			
BNP		pg/ml	0-100 pg/ml
hsCRP		mg/L	0.0-40 mg/L
Pregnancy Test (women of childbearing age)			Negative (urine)
<input type="checkbox"/> Not applicable age or gender			< 5.0 mU/ml (quantitative blood)
Comments:			

PI Signature \_\_\_\_\_

Date: \_\_\_\_\_

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# Cardiovascular Cell Therapy Research Network

## TIME Protocol Workbook

FORM NO. CNB007

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 $\geq$ 21 years old at consent date
LVEF		Must be $\leq$ 45%
Temperature		Must be $<$ 100.4 °F
Hemoglobin		Must be $\geq$ 9.0 mg/dl
Platelets*		Must be $\geq$ 120K and $\leq$ 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.**



# Cardiovascular Cell Therapy Research Network

TIME Protocol Workbook

FORM NO. CNB007

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 <input type="checkbox"/>	No <input type="checkbox"/>
2. Is there any other reason you think this patient should not continue in the study? (If yes, please explain in the Comments)	Yes <input type="checkbox"/>	No <input type="checkbox"/>
3. If the patient has an LV thrombus or atrial fibrillation, does either condition require current anticoagulation therapy?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
4. Have there been any additional tests that have revealed evidence of LV thrombus that requires anticoagulation therapy?	Yes <input type="checkbox"/>	No <input type="checkbox"/>

Comments:

RNC Signature \_\_\_\_\_

Date: \_\_\_\_\_

PI Signature \_\_\_\_\_

Date: \_\_\_\_\_

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



# Cardiovascular Cell Therapy Research Network

## TIME Protocol Workbook

<b>FORM NO. CNB005</b>				
Acrostic Identifier:				
Study ID:				
Date source/workbook completed: ___/___/_____				
<b>Physical Exam (Day after Infusion)</b>				
Date of Exam: ___/___/___		<input type="checkbox"/> Visit is outside time window		Reason:
<input type="checkbox"/> Informed consent was revised since study start date				
Date patient reconsented: ___/___/___			Consent version:	
<b>Vital Signs</b>			<b>NYHA Class:</b>	
Weight:	_____ pounds		<input type="checkbox"/> I	
Temperature:	_____ °F	<input type="checkbox"/> oral	<input type="checkbox"/> auricle	<input type="checkbox"/> II
Respirations:	___ breaths/minute		<input type="checkbox"/> III	
Heart rate:	___ beats/minute		<input type="checkbox"/> IV	
Blood Pressure:	___ / ___	mmHg (supine)		<input type="checkbox"/> N/A
	SBP	DBP		
<b>Review of Systems:</b>				
Have changes occurred since previous visit?    Yes <input type="checkbox"/> No <input type="checkbox"/> (If no, skip to telemetry)				
<u>Review of Systems</u>	<u>Normal</u>	<u>Abnormal</u>	<u>Not Examined</u>	<u>Describe</u>
Skin	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
HEENT	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Lungs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
CV	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Abdomen	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Lymph Nodes	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Musculoskeletal	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Neurological	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Other: _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Telemetry</b>				
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:		



# Cardiovascular Cell Therapy Research Network

TIME Protocol Workbook

FORM NO. CNB005	
Acrostic Identifier:	
Study ID:	
Date source/workbook completed: ____/____/____	
<b>Physical Exam (Day after Infusion)</b>	
<b>Questions</b>	
Has the patient experienced an adverse event since receiving study product? (If yes, complete AE form)	Yes <input type="checkbox"/> No <input type="checkbox"/>
Have there been any changes to medications since receiving study product? (If yes, update medication form)	Yes <input type="checkbox"/> No <input type="checkbox"/>
Have there been any EKG changes from baseline? (see EKG form)	Yes <input type="checkbox"/> No <input type="checkbox"/>
If yes, are the changes clinically significant? (see EKG form)	Yes <input type="checkbox"/> No <input type="checkbox"/>
Was the temperature log given to the patient?	Yes <input type="checkbox"/> No <input type="checkbox"/>
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)	Yes <input type="checkbox"/> No <input type="checkbox"/>
<b>Verify patient consented to Biorepository before you draw Biorepository bloods.</b>	
Comments:	

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

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<b>FORM NO. CNB021</b>			
Acrostic Identifier:			
Study ID:			
<b>Laboratory Tests (Day after Infusion)</b>			
Date source/workbook completed: ___/___/_____			
<b>Date and time specimen obtained: Date: ___/___/___ Time: ___:___:___</b>			
<b>CBC with Differential</b>	<b>Result</b>	<b>Unit</b>	<b>Normal Range</b>
WBC		K/mm <sup>3</sup>	4.0-11.0 K/mm <sup>3</sup>
RBC		M/mm <sup>3</sup>	4.0-6.0 M/mm <sup>3</sup>
Hgb		gm/dL	12.0-17.5 gm/dL
Hct		%	33-53%
MCV		fL	78-100 fL
Platelets		K/mm <sup>3</sup>	135-450 K/mm <sup>3</sup>
<b>WBC Differential</b>			
Neutrophils		%	36-74%
Lymphocytes		%	12-45%
Monocytes		%	0-13%
Eosinophils		%	0-8%
Basophils		%	< 3.0%
<b>Cardiac Enzymes (Either Troponin T or Troponin I should be completed, NOT both.)</b>			
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
<b>Renal Panel</b>	<b>Result</b>	<b>Unit</b>	<b>Normal Range</b>
Na+		mmol/L	132-148 mmol/L
K+		mmol/L	3.3-5.5 mmol/L
Chloride		mmol/L	95-110 mmol/L
CO <sub>2</sub>		mmol/L	22-32 mmol/L
Glucose		mg/dL	65-110 mg/dL
BUN		mg/dL	5-26 mg/dL
Creatinine		mg/dL	0.4-1.5 mg/dL
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



<b>FORM NO. CNB021</b>			
Acrostic Identifier:			
Study ID:			
<b>Laboratory Tests (<i>Day after Infusion</i>)</b>			
<b>Hepatic Panel</b>			
Bilirubin-Total		mg/dL	0.0-1.5 mg/dL
Bilirubin-Direct		mg/dL	0.0-0.4 mg/dL
Total Protein		g/dL	6.0-8.5 g/dL
Alk Phos		U/L	30-150 U/L
ALT		U/L	0-50 U/L
AST		U/L	0-42 U/L
Comments:			

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

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<b>FORM NO. CNB024</b>	
Acrostic Identifier:	
Study ID:	
<b>ECG (Day after Infusion)</b>	
Date source/workbook completed: ____/____/____	
Date of Procedure:     /     /     Time: ____:____	
PR interval: 0.____ sec	QRS interval: 0.____ sec
QT interval: 0.____ sec	HR: ____ bpm
<input type="checkbox"/> ECG NORMAL <input type="checkbox"/> ECG NOT NORMAL	
<b>Note: If you select "ECG NORMAL", you are done with this form.</b>	
<b>Rhythm: (Choose all that apply)</b>	
<input type="checkbox"/> normal sinus rhythm <input type="checkbox"/> sinus arrhythmia <input type="checkbox"/> sinus bradycardia (<60 bpm) <input type="checkbox"/> sinus tachycardia (>100 bpm) <input type="checkbox"/> atrial fibrillation <input type="checkbox"/> atrial flutter <input type="checkbox"/> multifocal atrial tachycardia <input type="checkbox"/> supraventricular tachycardia <input type="checkbox"/> junctional tachycardia <input type="checkbox"/> ventricular bigeminy <input type="checkbox"/> ectopic atrial rhythm <input type="checkbox"/> ventricular tachycardia (< 30 seconds) > 120 bpm <i>(must fill in a &amp; b if this box is checked)</i>	<input type="checkbox"/> ventricular demand pacemaker (VVI) <input type="checkbox"/> atrial pacemaker <input type="checkbox"/> dual chamber pacemaker (DDD) <input type="checkbox"/> wandering pacemaker <input type="checkbox"/> accelerated idioventricular rhythm <input type="checkbox"/> atrial premature complexes <input type="checkbox"/> ventricular premature complexes (PVCs) <input type="checkbox"/> ventricular couplets <input type="checkbox"/> junctional rhythm <input type="checkbox"/> ventricular fibrillation
If ventricular tachycardia, please complete: a. Length: ____ complexes     b. Average Rate: ____ bpm	
If patient is on pacemaker (as indicated above), choose level of pacing: <input type="checkbox"/> 100% paced <input type="checkbox"/> intermittently paced <input type="checkbox"/> N/A <i>(If 100% paced, do not complete rest of form)</i>	
<b>AV Conduction Abnormalities (Choose one):</b> <span style="float: right;"><input type="checkbox"/> NONE</span>	
<input type="checkbox"/> AV block, 1st degree <input type="checkbox"/> AV block, 2nd degree Mobitz type 1 (Wenkebach) <input type="checkbox"/> AV block, 2nd degree Mobitz type 2 <input type="checkbox"/> AV block, 3rd degree	
<b>Abnormalities of P wave: (Choose all that apply)</b> <span style="float: right;"><input type="checkbox"/> NONE</span>	
<input type="checkbox"/> Left atrial enlargement <input type="checkbox"/> Right atrial enlargement	
<b>Abnormalities of QRS axis (Choose one):</b> <span style="float: right;"><input type="checkbox"/> NONE</span>	
<input type="checkbox"/> Left axis deviation(> -30°) <input type="checkbox"/> Right axis deviation (> +100°)	
<b>QRS voltage abnormalities: (Choose all that apply)</b> <span style="float: right;"><input type="checkbox"/> NONE</span>	
<input type="checkbox"/> Low voltage <input type="checkbox"/> Right ventricular hypertrophy <input type="checkbox"/> Left ventricular hypertrophy	



**Cardiovascular Cell Therapy Research Network**  
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FORM NO. CNB024						
Acrostic Identifier:						
Study ID:						
<b>ECG (Day after Infusion)</b>						
<b>Intraventricular conduction abnormalities: (Choose all that apply)</b>						<input type="checkbox"/> <b>NONE</b>
<input type="checkbox"/> Right bundle branch block, complete			<input type="checkbox"/> Left bundle branch block, complete			
<input type="checkbox"/> Right bundle branch block, incomplete			<input type="checkbox"/> Left bundle branch block, incomplete			
<input type="checkbox"/> Left anterior fascicular block			<input type="checkbox"/> Nonspecific intraventricular conduction disturbance			
<input type="checkbox"/> Left posterior fascicular block						
For each "Yes" response, check all locations that apply:						
Are Q waves present?	Y <input type="checkbox"/>	N <input type="checkbox"/>	Anterior <input type="checkbox"/>	Lateral <input type="checkbox"/>	Inferior <input type="checkbox"/>	
Is ST segment elevation present?	Y <input type="checkbox"/>	N <input type="checkbox"/>	Anterior <input type="checkbox"/>	Lateral <input type="checkbox"/>	Inferior <input type="checkbox"/>	
Is ST segment depression present?	Y <input type="checkbox"/>	N <input type="checkbox"/>	Anterior <input type="checkbox"/>	Lateral <input type="checkbox"/>	Inferior <input type="checkbox"/>	
Is T wave inversion present?	Y <input type="checkbox"/>	N <input type="checkbox"/>	Anterior <input type="checkbox"/>	Lateral <input type="checkbox"/>	Inferior <input type="checkbox"/>	
Is there evidence of posterior infarction?	Y <input type="checkbox"/>	N <input type="checkbox"/>	Pathologic R wave V <sub>1</sub> , V <sub>2</sub> <input type="checkbox"/>	Abn. ST depression V <sub>1</sub> , V <sub>2</sub> <input type="checkbox"/>	Abn. ST elevation V <sub>1</sub> , V <sub>2</sub> <input type="checkbox"/>	
Is there evidence of RV infarction (right precordial leads)?	Y <input type="checkbox"/>	N <input type="checkbox"/>	N/A <input type="checkbox"/>			
Are there nonspecific ST and/or T wave abnormalities present?	Y <input type="checkbox"/>	N <input type="checkbox"/>				
Comments:						

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

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





**Cardiovascular Cell Therapy Research Network**  
TIME Protocol Workbook

**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. CNB099      Screening/Demographics
2. CNB001      Eligibility
3. CNB003      Baseline Risk Factors & Other Cardiac History
4. CNB004      Baseline Non Cardiovascular Medical History
5. CNB011      Medication List\*
6. CNB012      Medication Allergies\*
7. CNB024      ECG (Baseline)
8. CNB006      Index Event (Revascularization)
9. CNB005      Baseline Physical Exam
10. CNB021      Baseline Laboratory Tests
11. CNB007      Treatment Checklist

\*CNB011 and CNB012 are on the same page

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Signature

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Date

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Printed Name



**Cardiovascular Cell Therapy Research Network**  
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**FORM COMPLETION ATTESTATION**

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

1. CNB005      Day of Infusion Physical Exam
2. CNB029      Bone Marrow Aspiration
3. CNB031      Study Product Infusion

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Signature

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Date

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Printed Name



**Cardiovascular Cell Therapy Research Network**  
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**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. CNB005      Day after Infusion Physical Exam
2. CNB021      Day after Infusion Laboratory Tests
3. CNB024      ECG

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Signature

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Date

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Printed Name



**Cardiovascular Cell Therapy Research Network**  
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**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 CCTR web application, or a missing form has been noted.

1. CNB005      Month 1 Physical Exam
2. CNB022      Month 1 Laboratory Tests
3. CNB024      ECG
4. CNB023      Holter

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed Name



**Cardiovascular Cell Therapy Research Network**  
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**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. CNB005      Month 3 Physical Exam
2. CNB022      Month 3 Laboratory Tests

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Signature

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Date

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Printed Name



**Cardiovascular Cell Therapy Research Network**  
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**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 CCTR web application, or a missing form has been noted.

- 1. CNB005      Month 6 Physical Exam
- 2. CNB022      Month 6 Laboratory Tests
- 3. CNB024      ECG

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed Name



**Cardiovascular Cell Therapy Research Network**  
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**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 CCTR web application, or a missing form has been noted.

- 1. CNB005      Month 12 Physical Exam
- 2. CNB022      Month 12 Laboratory Tests

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed Name



**Cardiovascular Cell Therapy Research Network**  
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**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. CNB005      Month 24 Physical Exam
2. CNB022      Month 24 Laboratory Tests

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Signature

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Date

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Printed Name





# Cardiovascular Cell Therapy Research Network

## TIME Protocol Workbook

FORM NO. CNB005				
Acrostic Identifier:				
Study ID:				
Date source/workbook completed: ___/___/_____				
<b>Physical Exam (Month 1)</b>				
Date of Exam: ___/___/___		<input type="checkbox"/> Visit is outside time window	Reason:	
<input type="checkbox"/> Informed consent was revised since study start date				
Date patient reconsented: ___/___/___		Consent version:		
<b>Vital Signs</b>			<b>NYHA Class:</b>	
Weight:	_____ pounds		<input type="checkbox"/> I	
Temperature:	_____°F	<input type="checkbox"/> oral <input type="checkbox"/> auricle	<input type="checkbox"/> II	
Respirations:	___ __ breaths/minute		<input type="checkbox"/> III	
Heart rate:	___ __ beats/minute		<input type="checkbox"/> IV	
Blood Pressure:	___ ___ / ___ ___ mmHg (supine)		<input type="checkbox"/> N/A	
	SBP	DBP		
<b>Review of Systems:</b>				
Have changes occurred since previous visit?    Yes <input type="checkbox"/> No <input type="checkbox"/> (If no, table is complete)				
<u>Review of Systems</u>	<u>Normal</u>	<u>Abnormal</u>	<u>Not Examined</u>	<u>Describe</u>
Skin	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
HEENT	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Lungs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
CV	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Abdomen	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Lymph Nodes	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Musculoskeletal	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Neurological	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Other: _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	



# Cardiovascular Cell Therapy Research Network

## TIME Protocol Workbook

FORM NO. CNB005	
Acrostic Identifier:	
Study ID:	
Date source/workbook completed: ____/____/____	
<b>Physical Exam (Month 1)</b>	
<b>Questions</b>	
Has the patient experienced a new adverse event since the last follow-up visit? (If yes, complete AE form)	Yes <input type="checkbox"/> No <input type="checkbox"/>
Have there been any changes to medications since the last follow-up visit? (If yes, update medication form)	Yes <input type="checkbox"/> No <input type="checkbox"/>
Have there been any ECG changes from baseline? (see ECG form)	Yes <input type="checkbox"/> No <input type="checkbox"/>
If yes, are the changes clinically significant? (see ECG form)	Yes <input type="checkbox"/> No <input type="checkbox"/>
Were there any significant findings on the Holter report? (see Holter form)	Yes <input type="checkbox"/> No <input type="checkbox"/>
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)	Yes <input type="checkbox"/> No <input type="checkbox"/>
<b>Verify patient consented to Biorepository before you draw Biorepository bloods.</b>	
Comments:	

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



# Cardiovascular Cell Therapy Research Network

## TIME Protocol Workbook

<b>FORM NO. CNB022</b>			
Acrostic Identifier:			
Study ID:			
Date source/workbook completed: ___/___/_____			
<b>Laboratory Tests (Month 1)</b>			
Date and time specimen obtained:    Date: ___/___/___    Time: ___:___			
<b>CBC with Differential</b>	<b>Result</b>	<b>Unit</b>	<b>Normal Range</b>
WBC		K/mm <sup>3</sup>	4.0-11.0 K/mm <sup>3</sup>
RBC		M/mm <sup>3</sup>	4.0-6.0 M/mm <sup>3</sup>
Hgb		gm/dL	12.0-17.5 gm/dL
Hct		%	33-53%
MCV		fL	78-100 fL
Platelets		K/mm <sup>3</sup>	135-450 K/mm <sup>3</sup>
<b>WBC Differential</b>			
Neutrophils		%	36-74%
Lymphocytes		%	12-45%
Monocytes		%	0-13%
Eosinophils		%	0-8%
Basophils		%	< 3.0%
<b>Hepatic Panel</b>			
Bilirubin-Total		mg/dL	0.0-1.5 mg/dL
Bilirubin-Direct		mg/dL	0.0-0.4 mg/dL
Total Protein		g/dL	6.0-8.5 g/dL
Alk Phos		U/L	30-150 U/L
ALT		U/L	0-50 U/L
AST		U/L	0-42 U/L
Comments:			

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

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



<b>FORM NO. CNB024</b>	
Acrostic Identifier:	
Study ID:	
Date source/workbook completed: ____/____/____	
<b>ECG (Month 1)</b>	
Date of Procedure:     /     /     Time: ____:____	
PR interval: 0.____ sec    QRS interval: 0.____ sec    QT interval: 0.____ sec    HR: ____ bpm	
<input type="checkbox"/> ECG NORMAL <input type="checkbox"/> ECG NOT NORMAL	
<b>Note: If you select "ECG NORMAL", you are done with this form.</b>	
<b>Rhythm: (Choose all that apply)</b>	
<input type="checkbox"/> normal sinus rhythm <input type="checkbox"/> sinus arrhythmia <input type="checkbox"/> sinus bradycardia (<60 bpm) <input type="checkbox"/> sinus tachycardia (>100 bpm) <input type="checkbox"/> atrial fibrillation <input type="checkbox"/> atrial flutter <input type="checkbox"/> multifocal atrial tachycardia <input type="checkbox"/> supraventricular tachycardia <input type="checkbox"/> junctional tachycardia <input type="checkbox"/> ventricular bigeminy <input type="checkbox"/> ectopic atrial rhythm <input type="checkbox"/> ventricular tachycardia (< 30 seconds) > 120 bpm <i>(must fill in a &amp; b if this box is checked)</i> If ventricular tachycardia, please complete: a. Length: ____ complexes     b. Average Rate: ____ bpm	<input type="checkbox"/> ventricular demand pacemaker (VVI) <input type="checkbox"/> atrial pacemaker <input type="checkbox"/> dual chamber pacemaker (DDD) <input type="checkbox"/> wandering pacemaker <input type="checkbox"/> accelerated idioventricular rhythm <input type="checkbox"/> atrial premature complexes <input type="checkbox"/> ventricular premature complexes (PVCs) <input type="checkbox"/> ventricular couplets <input type="checkbox"/> junctional rhythm <input type="checkbox"/> ventricular fibrillation
If patient is on pacemaker (as indicated above), choose level of pacing:	
<input type="checkbox"/> 100% paced <input type="checkbox"/> intermittently paced <input type="checkbox"/> N/A <i>(If 100% paced, do not complete rest of form)</i>	
<b>AV Conduction Abnormalities (Choose one):</b>	
<input type="checkbox"/> AV block, 1st degree <input type="checkbox"/> AV block, 2nd degree Mobitz type 1 (Wenkebach) <input type="checkbox"/> AV block, 2nd degree Mobitz type 2 <input type="checkbox"/> AV block, 3rd degree	<input type="checkbox"/> NONE
<b>Abnormalities of P wave: (Choose all that apply)</b>	
<input type="checkbox"/> Left atrial enlargement <input type="checkbox"/> Right atrial enlargement	<input type="checkbox"/> NONE
<b>Abnormalities of QRS axis (Choose one):</b>	
<input type="checkbox"/> Left axis deviation(> -30°) <input type="checkbox"/> Right axis deviation (> +100°)	<input type="checkbox"/> NONE
<b>QRS voltage abnormalities: (Choose all that apply)</b>	
<input type="checkbox"/> Low voltage <input type="checkbox"/> Right ventricular hypertrophy <input type="checkbox"/> Left ventricular hypertrophy	<input type="checkbox"/> NONE



**Cardiovascular Cell Therapy Research Network**  
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FORM NO. CNB024					
Acrostic Identifier:					
Study ID:					
Date source/workbook completed: ___/___/_____					
<b>ECG (Month 1)</b>					
Intraventricular conduction abnormalities: (Choose all that apply)					<input type="checkbox"/> NONE
<input type="checkbox"/> Right bundle branch block, complete			<input type="checkbox"/> Left bundle branch block, complete		
<input type="checkbox"/> Right bundle branch block, incomplete			<input type="checkbox"/> Left bundle branch block, incomplete		
<input type="checkbox"/> Left anterior fascicular block			<input type="checkbox"/> Nonspecific intraventricular conduction disturbance		
<input type="checkbox"/> Left posterior fascicular block					
For each "Yes" response, check all locations that apply:					
Are Q waves present?	Y <input type="checkbox"/>	N <input type="checkbox"/>	Anterior <input type="checkbox"/>	Lateral <input type="checkbox"/>	Inferior <input type="checkbox"/>
Is ST segment elevation present?	Y <input type="checkbox"/>	N <input type="checkbox"/>	Anterior <input type="checkbox"/>	Lateral <input type="checkbox"/>	Inferior <input type="checkbox"/>
Is ST segment depression present?	Y <input type="checkbox"/>	N <input type="checkbox"/>	Anterior <input type="checkbox"/>	Lateral <input type="checkbox"/>	Inferior <input type="checkbox"/>
Is T wave inversion present?	Y <input type="checkbox"/>	N <input type="checkbox"/>	Anterior <input type="checkbox"/>	Lateral <input type="checkbox"/>	Inferior <input type="checkbox"/>
Is there evidence of posterior infarction?	Y <input type="checkbox"/>	N <input type="checkbox"/>	Pathologic R wave V <sub>1</sub> , V <sub>2</sub> <input type="checkbox"/>	Abn. ST depression V <sub>1</sub> , V <sub>2</sub> <input type="checkbox"/>	Abn. ST elevation V <sub>1</sub> , V <sub>2</sub> <input type="checkbox"/>
Is there evidence of RV infarction (right precordial leads)?	Y <input type="checkbox"/>	N <input type="checkbox"/>	N/A <input type="checkbox"/>		
Are there nonspecific ST and/or T wave abnormalities present?	Y <input type="checkbox"/>	N <input type="checkbox"/>			
Comments:					

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

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



# Cardiovascular Cell Therapy Research Network

TIME Protocol Workbook

FORM NO. CNB023

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: \_\_\_\_\_

### Ventricular Arrhythmia Summary:

Single/PVC: \_\_\_\_\_ beats

Couplets: \_\_\_\_\_

Total number of NSVT Runs ( $\geq 3$  beats) \_\_\_\_\_

Number of beats in longest NSVT run \_\_\_\_\_

Total number of sustained ventricular tachycardia runs ( $\geq 30$  secs) \_\_\_\_\_

### 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. @ \_\_\_\_:\_\_\_\_

### 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 \_\_\_\_\_



# Cardiovascular Cell Therapy Research Network

## TIME Protocol Workbook

FORM NO. CNB005				
Acrostic Identifier:				
Study ID:				
Date source form completed: ___ / ___ / ___				
<b>Physical Exam (Month 3)</b>				
Date of Exam: ___ / ___ / ___		<input type="checkbox"/> Visit is outside time window		Reason:
<input type="checkbox"/> Informed consent was revised since study start date				
Date patient reconsented: ___ / ___ / ___		Consent version:		
<b>Vital Signs</b>			<b>NYHA Class:</b>	
Weight:	_____ pounds		<input type="checkbox"/> I	
Temperature:	_____ °F	<input type="checkbox"/> oral	<input type="checkbox"/> auricle	<input type="checkbox"/> II
Respirations:	__ __ breaths/minute		<input type="checkbox"/> III	
Heart rate:	__ __ __ beats/minute		<input type="checkbox"/> IV	
Blood Pressure:	__ __ __ / __ __ __ mmHg (supine)		<input type="checkbox"/> N/A	
	SBP	DBP		
<b>Review of Systems:</b>				
Have changes occurred since previous visit? Yes <input type="checkbox"/> No <input type="checkbox"/> (If no, table is complete)				
<u>Review of Systems</u>	<u>Normal</u>	<u>Abnormal</u>	<u>Not Examined</u>	<u>Describe</u>
Skin	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
HEENT	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Lungs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
CV	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Abdomen	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Lymph Nodes	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Musculoskeletal	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Neurological	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Other: _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	



# Cardiovascular Cell Therapy Research Network

TIME Protocol Workbook

FORM NO. CNB005	
Acrostic Identifier:	
Study ID:	
Date source form completed: ____ / ____ / ____	
<b>Physical Exam (Month 3)</b>	
<b>Questions</b>	
Has the patient experienced a new adverse event since the last follow-up visit? (If yes, complete AE form)	Yes <input type="checkbox"/> No <input type="checkbox"/>
Have there been any changes to medications since the last follow-up visit? (If yes, update medication form)	Yes <input type="checkbox"/> No <input type="checkbox"/>
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)	Yes <input type="checkbox"/> No <input type="checkbox"/>
<b>Verify patient consented to Biorepository before you draw Biorepository bloods.</b>	
Comments:	

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





<b>FORM NO. CNB022</b>			
Acrostic Identifier:			
Study ID:			
Date form completed: ____ / ____ / ____			
<b>Laboratory Tests (Month 3)</b>			
Date and time specimen obtained:    Date: ____ / ____ / ____    Time: ____:____			
<b>CBC with Differential</b>	<b>Result</b>	<b>Unit</b>	<b>Normal Range</b>
WBC		K/mm <sup>3</sup>	4.0-11.0 K/mm <sup>3</sup>
RBC		M/mm <sup>3</sup>	4.0-6.0 M/mm <sup>3</sup>
Hgb		gm/dL	12.0-17.5 gm/dL
Hct		%	33-53%
MCV		fL	78-100 fL
Platelets		K/mm <sup>3</sup>	135-450 K/mm <sup>3</sup>
<b>WBC Differential</b>			
Neutrophils		%	36-74%
Lymphocytes		%	12-45%
Monocytes		%	0-13%
Eosinophils		%	0-8%
Basophils		%	< 3.0%
<b>Hepatic Panel</b>			
Bilirubin-Total		mg/dL	0.0-1.5 mg/dL
Bilirubin-Direct		mg/dL	0.0-0.4 mg/dL
Total Protein		g/dL	6.0-8.5 g/dL
Alk Phos		U/L	30-150 U/L
ALT		U/L	0-50 U/L
AST		U/L	0-42 U/L
Comments:			

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

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



**Cardiovascular Cell Therapy Research Network**  
TIME Protocol Workbook

FORM NO. CNB005				
Acrostic Identifier:				
Study ID:				
Date form completed:				
<b>Physical Exam (Month 6)</b>				
Date of Exam: ___ / ___ / ___		<input type="checkbox"/> Visit is outside time window		Reason:
<input type="checkbox"/> Informed consent was revised since study start date				
Date patient reconsented: ___ / ___ / ___		Consent version:		
<b>Vital Signs</b>			<b>NYHA Class:</b>	
Weight:	_____ pounds		<input type="checkbox"/> I	
Temperature:	_____°F	<input type="checkbox"/> oral	<input type="checkbox"/> auricle	<input type="checkbox"/> II
Respirations:	___ ___ breaths/minute		<input type="checkbox"/> III	
Heart rate:	___ ___ ___ beats/minute		<input type="checkbox"/> IV	
Blood Pressure:	___ ___ / ___ ___	mmHg (supine)	<input type="checkbox"/> N/A	
	SBP	DBP		
<b>Review of Systems:</b>				
Have changes occurred since previous visit?    Yes <input type="checkbox"/> No <input type="checkbox"/> If no, the table is complete.				
<u>Review of Systems</u>	<u>Normal</u>	<u>Abnormal</u>	<u>Not Examined</u>	<u>Describe</u>
Skin	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
HEENT	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Lungs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
CV	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Abdomen	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Lymph Nodes	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Musculoskeletal	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Neurological	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Other: _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	



# Cardiovascular Cell Therapy Research Network

TIME Protocol Workbook

FORM NO. CNB005		
Acrostic Identifier:		
Study ID:		
Date form completed:		
<b>Physical Exam (Month 6)</b>		
<b>Questions</b>		
Has the patient experienced an adverse event since receiving study product? (If yes, complete AE form)	Yes <input type="checkbox"/> No <input type="checkbox"/>	
Have there been any changes to medications since receiving study product? (If yes, update medication form)	Yes <input type="checkbox"/> No <input type="checkbox"/>	
Have there been any ECG changes from baseline? (see ECG form)	Yes <input type="checkbox"/> No <input type="checkbox"/>	
If yes, are the changes clinically significant? (see ECG form)	Yes <input type="checkbox"/> No <input type="checkbox"/>	
Was the Echo completed to send to the Core Lab? (If no, please enter a reason in Comments)	Yes <input type="checkbox"/> No <input type="checkbox"/>	
Was the MRI completed to send to the Core Lab? (If no, please enter a reason in Comments)	Yes <input type="checkbox"/> No <input type="checkbox"/>	MRI contraindicated <input type="checkbox"/>
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)	Yes <input type="checkbox"/> No <input type="checkbox"/>	
<b>Verify patient consented to Biorepository before you draw Biorepository bloods.</b>		
Comments:		



# Cardiovascular Cell Therapy Research Network

## TIME Protocol Workbook

FORM NO. CNB022			
Acrostic Identifier:			
Study ID:			
Date source/workbook completed: ___/___/_____			
<b>Laboratory Tests (Month 6)</b>			
Date and time specimen obtained: Date: ___/___/___ Time: ___:___			
<b>CBC with Differential</b>	<b>Result</b>	<b>Unit</b>	<b>Normal Range</b>
WBC		K/mm <sup>3</sup>	4.0-11.0 K/mm <sup>3</sup>
RBC		M/mm <sup>3</sup>	4.0-6.0 M/mm <sup>3</sup>
Hgb		gm/dL	12.0-17.5 gm/dL
Hct		%	33-53%
MCV		fL	78-100 fL
Platelets		K/mm <sup>3</sup>	135-450 K/mm <sup>3</sup>
<b>WBC Differential</b>			
Neutrophils		%	36-74%
Lymphocytes		%	12-45%
Monocytes		%	0-13%
Eosinophils		%	0-8%
Basophils		%	< 3.0%
<b>Hepatic Panel</b>			
Bilirubin-Total		mg/dL	0.0-1.5 mg/dL
Bilirubin-Direct		mg/dL	0.0-0.4 mg/dL
Total Protein		g/dL	6.0-8.5 g/dL
Alk Phos		U/L	30-150 U/L
ALT		U/L	0-50 U/L
AST		U/L	0-42 U/L
<b>Other Tests</b>			
BNP		pg/ml	0-100 pg/ml
Comments:			

PI Signature \_\_\_\_\_

Date: \_\_\_\_\_

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



<b>FORM NO. CNB024</b>	
Acrostic Identifier:	
Study ID:	
Date source/workbook completed: ____/____/____	
<b>ECG (Month 6)</b>	
Date of Procedure:     /     /     Time: ____:____	
PR interval: 0.____ sec    QRS interval: 0.____ sec    QT interval: 0.____ sec    HR: ____ bpm	
<input type="checkbox"/> ECG NORMAL <input type="checkbox"/> ECG NOT NORMAL	
<b>Note: If you select "ECG NORMAL", you are done with this form.</b>	
<b>Rhythm: (Choose all that apply)</b>	
<input type="checkbox"/> normal sinus rhythm	<input type="checkbox"/> ventricular demand pacemaker (VVI)
<input type="checkbox"/> sinus arrhythmia	<input type="checkbox"/> atrial pacemaker
<input type="checkbox"/> sinus bradycardia (<60 bpm)	<input type="checkbox"/> dual chamber pacemaker (DDD)
<input type="checkbox"/> sinus tachycardia (>100 bpm)	<input type="checkbox"/> wandering pacemaker
<input type="checkbox"/> atrial fibrillation	<input type="checkbox"/> accelerated idioventricular rhythm
<input type="checkbox"/> atrial flutter	<input type="checkbox"/> atrial premature complexes
<input type="checkbox"/> multifocal atrial tachycardia	<input type="checkbox"/> ventricular premature complexes (PVCs)
<input type="checkbox"/> supraventricular tachycardia	<input type="checkbox"/> ventricular couplets
<input type="checkbox"/> junctional tachycardia	<input type="checkbox"/> junctional rhythm
<input type="checkbox"/> ventricular bigeminy	<input type="checkbox"/> ventricular fibrillation
<input type="checkbox"/> ectopic atrial rhythm	
<input type="checkbox"/> ventricular tachycardia (< 30 seconds) > 120 bpm <i>(must fill in a &amp; b if this box is checked)</i>	
If ventricular tachycardia, please complete:	
a. Length: ____ complexes	b. Average Rate: ____ bpm
If patient is on pacemaker (as indicated above), choose level of pacing:	
<input type="checkbox"/> 100% paced	<input type="checkbox"/> intermittently paced <input type="checkbox"/> N/A <i>(If 100% paced, do not complete rest of form)</i>
<b>AV Conduction Abnormalities (Choose one):</b> <span style="float: right;"><input type="checkbox"/> NONE</span>	
<input type="checkbox"/> AV block, 1st degree <input type="checkbox"/> AV block, 2nd degree Mobitz type 1 (Wenkebach) <input type="checkbox"/> AV block, 2nd degree Mobitz type 2 <input type="checkbox"/> AV block, 3rd degree	
<b>Abnormalities of P wave: (Choose all that apply)</b> <span style="float: right;"><input type="checkbox"/> NONE</span>	
<input type="checkbox"/> Left atrial enlargement <input type="checkbox"/> Right atrial enlargement	
<b>Abnormalities of QRS axis (Choose one):</b> <span style="float: right;"><input type="checkbox"/> NONE</span>	
<input type="checkbox"/> Left axis deviation(> -30°) <input type="checkbox"/> Right axis deviation (> +100°)	
<b>QRS voltage abnormalities: (Choose all that apply)</b> <span style="float: right;"><input type="checkbox"/> NONE</span>	
<input type="checkbox"/> Low voltage <input type="checkbox"/> Right ventricular hypertrophy <input type="checkbox"/> Left ventricular hypertrophy	



**Cardiovascular Cell Therapy Research Network**  
TIME Protocol Workbook

<b>FORM NO. CNB024</b>					
Acrostic Identifier:					
Study ID:					
Date source/workbook completed: ____/____/____					
<b>ECG (Month 6)</b>					
<b>Intraventricular conduction abnormalities: (Choose all that apply)</b>					<input type="checkbox"/> <b>NONE</b>
<input type="checkbox"/> Right bundle branch block, complete			<input type="checkbox"/> Left bundle branch block, complete		
<input type="checkbox"/> Right bundle branch block, incomplete			<input type="checkbox"/> Left bundle branch block, incomplete		
<input type="checkbox"/> Left anterior fascicular block			<input type="checkbox"/> Nonspecific intraventricular conduction disturbance		
<input type="checkbox"/> Left posterior fascicular block					
For each "Yes" response, check all locations that apply:					
Are Q waves present?	Y <input type="checkbox"/>	N <input type="checkbox"/>	Anterior <input type="checkbox"/>	Lateral <input type="checkbox"/>	Inferior <input type="checkbox"/>
Is ST segment elevation present?	Y <input type="checkbox"/>	N <input type="checkbox"/>	Anterior <input type="checkbox"/>	Lateral <input type="checkbox"/>	Inferior <input type="checkbox"/>
Is ST segment depression present?	Y <input type="checkbox"/>	N <input type="checkbox"/>	Anterior <input type="checkbox"/>	Lateral <input type="checkbox"/>	Inferior <input type="checkbox"/>
Is T wave inversion present?	Y <input type="checkbox"/>	N <input type="checkbox"/>	Anterior <input type="checkbox"/>	Lateral <input type="checkbox"/>	Inferior <input type="checkbox"/>
Is there evidence of posterior infarction?	Y <input type="checkbox"/>	N <input type="checkbox"/>	Pathologic R wave V <sub>1</sub> , V <sub>2</sub> <input type="checkbox"/>	Abn. ST depression V <sub>1</sub> , V <sub>2</sub> <input type="checkbox"/>	Abn. ST elevation V <sub>1</sub> , V <sub>2</sub> <input type="checkbox"/>
Is there evidence of RV infarction (right precordial leads)?	Y <input type="checkbox"/>	N <input type="checkbox"/>	N/A <input type="checkbox"/>		
Are there nonspecific ST and/or T wave abnormalities present?	Y <input type="checkbox"/>	N <input type="checkbox"/>			
Comments:					

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

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



# Cardiovascular Cell Therapy Research Network

TIME Protocol Workbook

FORM NO. CNB005				
Acrostic Identifier:				
Study ID:				
Date form completed: ___ / ___ / ___				
<b>Physical Exam (Month 12)</b>				
Date of Exam: ___ / ___ / ___		<input type="checkbox"/> Visit is outside time window		Reason:
<input type="checkbox"/> Informed consent was revised since study start date				
Date patient reconsented: ___ / ___ / ___		Consent version:		
<b>Vital Signs</b>			<b>NYHA Class:</b>	
Weight:	_____ pounds		<input type="checkbox"/> I	
Temperature:	_____ °F	<input type="checkbox"/> oral	<input type="checkbox"/> auricle	<input type="checkbox"/> II
Respirations:	___ ___ breaths/minute		<input type="checkbox"/> III	
Heart rate:	___ ___ beats/minute		<input type="checkbox"/> IV	
Blood Pressure:	___ ___ / ___ ___ mmHg (supine)		<input type="checkbox"/> N/A	
	SBP	DBP		
<b>Review of Systems:</b>				
Have changes occurred since previous visit? Yes <input type="checkbox"/> No <input type="checkbox"/> (If no, table is complete)				
<u>Review of Systems</u>	<u>Normal</u>	<u>Abnormal</u>	<u>Not Examined</u>	<u>Describe</u>
Skin	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
HEENT	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Lungs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
CV	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Abdomen	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Lymph Nodes	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Musculoskeletal	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Neurological	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Other: _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	



FORM NO. CNB005
Acrostic Identifier:
Study ID:
Date form completed: ____ / ____ / ____
<b>Physical Exam (Month 12)</b>
<b>Questions</b>
Has the patient experienced a new adverse event since the last follow-up visit? (If yes, complete AE form) Yes <input type="checkbox"/> No <input type="checkbox"/>
Have there been any changes to medications since the last follow-up visit? (If yes, update Medication form) Yes <input type="checkbox"/> No <input type="checkbox"/>
Was the safety MRI completed? (If no, enter a reason in Comments) Yes <input type="checkbox"/> No <input type="checkbox"/>
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 <input type="checkbox"/> No <input type="checkbox"/>
Comments:

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





<b>FORM NO. CNB022</b>			
Acrostic Identifier:			
Study ID:			
Date form completed: ____ / ____ / ____			
<b>Laboratory Tests (Month 12)</b>			
Date and time specimen obtained:    Date: ____ / ____ / ____    Time: ____ : ____			
<b>CBC with Differential</b>	<b>Result</b>	<b>Unit</b>	<b>Normal Range</b>
WBC		K/mm <sup>3</sup>	4.0-11.0 K/mm <sup>3</sup>
RBC		M/mm <sup>3</sup>	4.0-6.0 M/mm <sup>3</sup>
Hgb		gm/dL	12.0-17.5 gm/dL
Hct		%	33-53%
MCV		fL	78-100 fL
Platelets		K/mm <sup>3</sup>	135-450 K/mm <sup>3</sup>
<b>WBC Differential</b>			
Neutrophils		%	36-74%
Lymphocytes		%	12-45%
Monocytes		%	0-13%
Eosinophils		%	0-8%
Basophils		%	< 3.0%
<b>Hepatic Panel</b>			
Bilirubin-Total		mg/dL	0.0-1.5 mg/dL
Bilirubin-Direct		mg/dL	0.0-0.4 mg/dL
Total Protein		g/dL	6.0-8.5 g/dL
Alk Phos		U/L	30-150 U/L
ALT		U/L	0-50 U/L
AST		U/L	0-42 U/L
<b>Other Tests</b>			
BNP		pg/ml	0-100 pg/ml
Comments:			

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

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



# Cardiovascular Cell Therapy Research Network

TIME Protocol Workbook

FORM NO. CNB005

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		<input type="checkbox"/> I
Temperature: _____ °F <input type="checkbox"/> oral <input type="checkbox"/> auricle		<input type="checkbox"/> II
Respirations: ___ breaths/minute		<input type="checkbox"/> III
Heart rate: ___ beats/minute		<input type="checkbox"/> IV
Blood Pressure: _____ / _____ mmHg (supine) SBP DBP		<input type="checkbox"/> 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	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
HEENT	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Lungs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
CV	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Abdomen	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Lymph Nodes	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Musculoskeletal	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Neurological	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Other: _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	



# Cardiovascular Cell Therapy Research Network

TIME Protocol Workbook

FORM NO. CNB005	
Acrostic Identifier:	
Study ID:	
Date form completed: ____ / ____ / ____	
<b>Physical Exam (Month 24)</b>	
<b>Questions</b>	
Has the patient experienced a new adverse event since the last follow-up visit? (If yes, complete AE form)	Yes <input type="checkbox"/> No <input type="checkbox"/>
Have there been any changes to medications since the last follow-up visit? (If yes, update Medication form)	Yes <input type="checkbox"/> No <input type="checkbox"/>
Was the safety MRI completed? (If no, enter a reason in Comments)	Yes <input type="checkbox"/> No <input type="checkbox"/>
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 <input type="checkbox"/> No <input type="checkbox"/>
Comments:	

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



<b>FORM NO. CNB022</b>			
Acrostic Identifier:			
Study ID:			
Date form completed: ____ / ____ / ____			
<b>Laboratory Tests (Month 24)</b>			
Date and time specimen obtained:    Date: ____ / ____ / ____    Time: ____:____			
<b>CBC with Differential</b>	<b>Result</b>	<b>Unit</b>	<b>Normal Range</b>
WBC		K/mm <sup>3</sup>	4.0-11.0 K/mm <sup>3</sup>
RBC		M/mm <sup>3</sup>	4.0-6.0 M/mm <sup>3</sup>
Hgb		gm/dL	12.0-17.5 gm/dL
Hct		%	33-53%
MCV		fL	78-100 fL
Platelets		K/mm <sup>3</sup>	135-450 K/mm <sup>3</sup>
<b>WBC Differential</b>			
Neutrophils		%	36-74%
Lymphocytes		%	12-45%
Monocytes		%	0-13%
Eosinophils		%	0-8%
Basophils		%	< 3.0%
<b>Hepatic Panel</b>			
Bilirubin-Total		mg/dL	0.0-1.5 mg/dL
Bilirubin-Direct		mg/dL	0.0-0.4 mg/dL
Total Protein		g/dL	6.0-8.5 g/dL
Alk Phos		U/L	30-150 U/L
ALT		U/L	0-50 U/L
AST		U/L	0-42 U/L
<b>Other Tests</b>			
BNP		pg/ml	0-100 pg/ml
Comments:			

PI Signature \_\_\_\_\_

Date: \_\_\_\_\_

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



# Cardiovascular Cell Therapy Research Network

TIME Protocol Workbook

FORM NO. CNB005

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		<input type="checkbox"/> I
Temperature: _____. ____ °F <input type="checkbox"/> oral <input type="checkbox"/> auricle		<input type="checkbox"/> II
Respirations: ____ breaths/minute		<input type="checkbox"/> III
Heart rate: ____ beats/minute		<input type="checkbox"/> IV
Blood Pressure: ____ / ____ mmHg (supine) SBP          DBP		<input type="checkbox"/> 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	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
HEENT	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Lungs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
CV	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Abdomen	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Lymph Nodes	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Musculoskeletal	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Neurological	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Other: _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

### 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

Comments: \_\_\_\_\_

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



# Cardiovascular Cell Therapy Research Network

## TIME Protocol Workbook

<b>FORM NO. CNB026</b>			
Acrostic Identifier:			
Study ID:			
Date form completed: ____ / ____ / ____			
<b>Laboratory Tests (Interim)</b>			
Reason for Interim Lab:			
Date and time specimen obtained: Date: ____ / ____ / ____ Time: ____ : ____			
<b>CBC with Differential</b>	<b>Result</b>	<b>Unit</b>	<b>Normal Range</b>
WBC		K/mm <sup>3</sup>	4.0-11.0 K/mm <sup>3</sup>
RBC		M/mm <sup>3</sup>	4.0-6.0 M/mm <sup>3</sup>
Hgb		gm/dL	12.0-17.5 gm/dL
Hct		%	33-53%
MCV		fL	78-100 fL
Platelets		K/mm <sup>3</sup>	135-450 K/mm <sup>3</sup>
<b>WBC Differential</b>			
Neutrophils		%	36-74%
Lymphocytes		%	12-45%
Monocytes		%	0-13%
Eosinophils		%	0-8%
Basophils		%	< 3.0%
<b>Cardiac Enzymes (Either Troponin T or Troponin I should be completed, NOT both.)</b>			
Troponin T		ng/ml	0.0-10 ng/ml
Troponin I		ng/ml	0.0-100 ng/ml
CK		U/L	25-10,000 U/L
CK-MB		ng/ml	0.0-250 ng/ml
<b>Renal Panel</b>			
Na+		mmol/L	132-148 mmol/L
K+		mmol/L	3.3-5.5 mmol/L
Chloride		mmol/L	95-110 mmol/L
CO <sub>2</sub>		mmol/L	22-32 mmol/L
Glucose		mg/dL	65-110 mg/dL
BUN		mg/dL	5-26 mg/dL
Creatinine		mg/dL	0.4-1.5 mg/dL
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



# Cardiovascular Cell Therapy Research Network

## TIME Protocol Workbook

FORM NO. CNB026			
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)			Negative (urine)
<input type="checkbox"/> Not applicable age or gender			< 5.0 mU/ml (quantitative blood)
Comments:			

PI Signature \_\_\_\_\_

Date: \_\_\_\_\_

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



# Cardiovascular Cell Therapy Research Network

TIME Protocol Workbook

FORM NO. CNB041												
Acrostic Identifier:												
Study ID:												
<b>Adverse Event Log</b>												
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 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)			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.												<input type="checkbox"/>
2.												<input type="checkbox"/>
3.												<input type="checkbox"/>
4.												<input type="checkbox"/>
5.												<input type="checkbox"/>
* 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 \_\_\_\_\_





## Cardiovascular Cell Therapy Research Network

TIME Protocol Workbook

FORM NO. CNB042

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 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)	Start Date ( ____ / ____ / ____ )	End Date ( ____ / ____ / ____ )	Outcome Status	Expectedness	Severity	Relationship to Study/Study Product	Outcome Attributed to SAE	Study Status	Narrative added* (progress note)
1.									<input type="checkbox"/>
2.									<input type="checkbox"/>
3.									<input type="checkbox"/>
4.									<input type="checkbox"/>
5.									<input type="checkbox"/>

\* 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 \_\_\_\_\_



# Cardiovascular Cell Therapy Research Network

TIME Protocol Workbook

FORM NO. CNB043		
<b>Is this unanticipated problem specific to an individual subject ?</b> <input type="checkbox"/> Yes <input type="checkbox"/> No		
Acrostic Identifier: <i>(fill in if answer to above is "Yes")</i>		
Study ID: <i>(fill in if answer to above is "Yes")</i>		
Site: <i>(fill in if answer to above is "No")</i>		
<i>(Note: If the UP does not apply to an individual subject, the Acrostic Identifier and Study ID remain blank)</i>		
Date form completed: ____ / ____ / ____		
<b>Unanticipated Problem (UP) Report</b>		
<b>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.</b>		
<b>These should be reported to the IRB within 10 working days.</b>		
Date of the Event: ____ / ____ / ____		
Date the site study team had knowledge of the Event: ____ / ____ / ____		
<b>This Event meets the criteria for an unanticipated problem because:</b>		
<input type="checkbox"/>	1	<b>Unanticipated:</b> 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.
<input type="checkbox"/>	2	<b>Related:</b> 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.
<input type="checkbox"/>	3	<b>Serious:</b> 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.
<b>Note: The event <u>must meet all</u> of the above criteria to be considered an unanticipated problem.</b>		
<b>Describe the type of event:</b>		
<input type="checkbox"/>	Accidental or unintentional change to the IRB-approved protocol that resulted in risk or has the potential to recur.	
<input type="checkbox"/>	Publication in the literature, safety monitoring report, or other findings indicating an unexpected change to the risks or potential benefits of the research.	
<input type="checkbox"/>	Complaint of a participant that indicates an unanticipated risk or which cannot be resolved by the research staff.	
<input type="checkbox"/>	A breach in confidentiality that may involve risk to that individual or others (e.g. compromised/stolen computer).	
<input type="checkbox"/>	Incarceration of a member of the research staff.	
<input type="checkbox"/>	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):		



# Cardiovascular Cell Therapy Research Network

TIME Protocol Workbook

FORM NO. CNB044

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:

<input type="checkbox"/>	1	The event resulted in an accidental or unintentional change to the IRB approved protocol and procedures without prior sponsor approval.
<input type="checkbox"/>	2	The event affected the participant's rights, safety, or welfare, or the integrity of the resultant data.

**Note: The event must meet at least one of the above criteria to be considered a protocol deviation/violation.**

Describe 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: \_\_\_\_\_

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### CCTRN Exemption/Waiver Documentation (DCC only)

CCTRN Medical Officer or Designee Review:

<b>Action Taken:</b>	<input type="checkbox"/> <b>Granted</b>	<input type="checkbox"/> <b>Not Granted</b>
<b>Waiver Acknowledgement:</b>	<input type="checkbox"/> <b>Received / Acknowledged</b>	

DCC Signature \_\_\_\_\_ Date: \_\_\_\_\_



# Cardiovascular Cell Therapy Research Network

## TIME Protocol Workbook

FORM NO. CNB048

Acrostic Identifier:

Study ID:

### Missing Form

Form Missing:	Reason/Comment:	Date of this Entry:
<input type="checkbox"/> BSL Risk Factors & Other Cardiac Hx		
<input type="checkbox"/> BSL Non Cardio. Med. Hx		
<input type="checkbox"/> BSL - Physical Exam		
<input type="checkbox"/> BSL - ECG		
<input type="checkbox"/> BSL - Labs		
<input type="checkbox"/> Medication allergies		
<input type="checkbox"/> Medication list		
<input type="checkbox"/> Index Event (Revascularization)		
<input type="checkbox"/> Bone Marrow Aspiration		
<input type="checkbox"/> Study Product Infusion		
<input type="checkbox"/> Day of Infusion - Phys. Exam		
<input type="checkbox"/> Day after Infusion - Phys. Exam		
<input type="checkbox"/> Day after Infusion - ECG		
<input type="checkbox"/> Day after Infusion - Labs		
<input type="checkbox"/> Mo 1 - Physical Exam		
<input type="checkbox"/> Mo 1 - Labs (F/U)		
<input type="checkbox"/> Mo 1 - ECG		
<input type="checkbox"/> Holter		
<input type="checkbox"/> Mo 3 - Physical Exam		
<input type="checkbox"/> Mo 3 - Labs (F/U)		
<input type="checkbox"/> Mo 6 - Physical Exam		
<input type="checkbox"/> Mo 6 - Labs (F/U)		
<input type="checkbox"/> Mo 6 - ECG		
<input type="checkbox"/> Mo 12 - Physical Exam		
<input type="checkbox"/> Mo 12 - Labs (F/U)		
<input type="checkbox"/> Mo 24 - Physical Exam		
<input type="checkbox"/> Mo 24 - Labs (F/U)		
<input type="checkbox"/> End of Study		



# Cardiovascular Cell Therapy Research Network

TIME Protocol Workbook

FORM NO. CNB051

Acrostic Identifier:

Study ID:

Date form completed: \_\_\_\_ / \_\_\_\_ / \_\_\_\_

### End of Study

Date of final follow-up study visit: \_\_\_\_ / \_\_\_\_ / \_\_\_\_

Reason for discharge from the study:

- |  |  |
|--|--|
| <input type="checkbox"/> Completed study   | Date of Discharge from Study: ____ / ____ / ____ |
| <input type="checkbox"/> Withdrawn         | Date of Discharge from Study: ____ / ____ / ____ |
| <input type="checkbox"/> Lost to follow-up | Date of Discharge from Study: ____ / ____ / ____ |
| <input type="checkbox"/> Screen Failure    | Date of Discharge from Study: ____ / ____ / ____ |

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

*Reasons that require follow-up:*

- |   |                     |
|---|---------------------|
| <input type="checkbox"/> Serious Adverse Event (until resolved) | Event Number: _____ |
| <input type="checkbox"/> Pregnancy (1 year post birth)          | Event Number: _____ |
| <input type="checkbox"/> Other                                  | Describe: _____     |

*Reasons that DO NOT require follow-up:*

- |   |                     |
|---|---------------------|
| <input type="checkbox"/> Death                        | Event Number: _____ |
| <input type="checkbox"/> Adverse Event                | Event Number: _____ |
| <input type="checkbox"/> Withdrawal of consent        |                     |
| <input type="checkbox"/> Protocol Deviation/Violation |                     |
| <input type="checkbox"/> Investigator Discretion      | Describe: _____     |
| <input type="checkbox"/> Sponsor Discretion           | Describe: _____     |
| <input type="checkbox"/> Other                        | Describe: _____     |

Please verify the following tasks are complete:

- |                          |  |
|--------------------------|--|
| <input type="checkbox"/> | All Informed Consents forms are properly signed/dated and available  |
| <input type="checkbox"/> | 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. |
| <input type="checkbox"/> | All source document data have been entered into the electronic CRF database  |
| <input type="checkbox"/> | All electronic CRFs have been submitted to the DCC   |
| <input type="checkbox"/> | I have reviewed all case report forms for this patient and found them to be in complete agreement with the source documents.                                     |
| <input type="checkbox"/> | 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 \_\_\_\_\_