



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

<b>FORM NO. CND001</b>				
Study ID: _____				
Date source form completed (mm/dd/yyyy): ____ / ____ / ____				
<b>PACE Screening Form</b>				
Date screened (mm/dd/yyyy): ____ / ____ / ____				
Sex:        M <input type="checkbox"/> F <input type="checkbox"/>				
Age: ____ (years)				
Hispanic, Latino or Spanish Origin:        Y <input type="checkbox"/> N <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"/>
How did the patient first find out about this study? Please choose the closest answer.				
<input type="checkbox"/> Cardiologist or other physician				
<input type="checkbox"/> Research nurse or other non-physician medical personnel				
<input type="checkbox"/> Clinicaltrials.gov website				
<input type="checkbox"/> Internet (not including clinicaltrials.gov)				
<input type="checkbox"/> Facebook or Twitter				
<input type="checkbox"/> Newspaper/Magazine				
<input type="checkbox"/> Hospital flyer or other print advertisement				
<input type="checkbox"/> Radio/TV				
<input type="checkbox"/> Referred by a friend or other non-medical person				
<input type="checkbox"/> Other (please specify): _____				
<input type="checkbox"/> No Response				
<b>Inclusion Criteria</b>				
1) Does the patient have atherosclerotic PAD with claudication (exercise induced pain, cramps, fatigue, or other equivalent discomfort involving large muscle groups of the leg(s) that is consistently relieved by rest)?			<input type="checkbox"/>	<input type="checkbox"/>
			Y	N
2) Does the patient have atypical leg pain (exertional leg pain that does not begin at rest or does not resolve consistently with rest) ?			<input type="checkbox"/>	<input type="checkbox"/>
			Y	N
3) Is the patient ≥ 40 years old?			<input type="checkbox"/>	<input type="checkbox"/>
			Y	N
4) Does the patient have a resting ankle-brachial index of < 0.90 OR a resting toe-brachial index of less than 0.70 at baseline testing?	ABI value: _____	TBI value: _____	<input type="checkbox"/>	<input type="checkbox"/>
			Y	N
				<input type="checkbox"/>
				Neither Available
5) Does the patient have significant stenosis or occlusion of infrainguinal arteries including the superficial femoral artery, popliteal artery and/or infrapopliteal arteries determined by: Duplex ultrasound imaging, lower extremity CTA, lower extremity MRA, or lower extremity catheter-based contrast arteriography?			<input type="checkbox"/>	<input type="checkbox"/>
			Y	N
				<input type="checkbox"/>
				Not Available



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<b>PACE Screening Form</b>			
6) Does the patient agree to participate in this trial? If no, please check a reason below (required): <ul style="list-style-type: none"> <li><input type="checkbox"/> Declined</li> <li><input type="checkbox"/> Does not want placebo</li> <li><input type="checkbox"/> Could not decide</li> <li><input type="checkbox"/> Too far / Transportation issues</li> <li><input type="checkbox"/> Family issues or concerns</li> <li><input type="checkbox"/> Unwilling to participate in study procedures and/or follow-up</li> <li><input type="checkbox"/> Too busy / Too much going on</li> <li><input type="checkbox"/> Other (please specify) _____</li> </ul>	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input type="checkbox"/> Not Available
<b>Exclusion Criteria</b>		<input type="checkbox"/> <b>No evidence in medical record of an exclusion</b>	
<i>If box above is checked, the rest can be blank, or select 1 or more criteria below for a screen failure.</i>			
7) Does the patient have presence of any musculoskeletal disease, cardiac or pulmonary, or neurological disease that limits the patient's ability to walk to fulfill protocol requirements (claudication must be the consistent primary exercise limitation)?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input type="checkbox"/> Not Available
8) Is the patient unable to complete the treadmill testing per protocol requirements?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input type="checkbox"/> Not Available
9) Is the patient able to walk for more than 12 minutes on the treadmill during treadmill testing?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input type="checkbox"/> Not Available
10) Does the patient identify both legs as equivocally symptomatic or alternate between symptomatic legs on the baseline treadmill tests?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input type="checkbox"/> Not Available
11) Does the patient have critical limb ischemia (Rutherford classes 4 or 5)?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input type="checkbox"/> Not Available
12) Has the patient had a recent (< 3 months) infrainguinal revascularization (surgery or endovascular revascularization) or is planned during the study period?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input type="checkbox"/> Not Available
13) Does the patient have peripheral pitting edema >2+?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input type="checkbox"/> Not Available
14) Is the patient pregnant, planning to become pregnant in the next 12 months, or lactating?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input type="checkbox"/> Not Available
15) Has the patient had a CHF hospitalization within the last 1 month prior to enrollment (as defined by the standard definitions of CHF and ACS by the AHA)?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input type="checkbox"/> Not Available
16) Has the patient had acute coronary syndrome within the last 1 month prior to enrollment (as defined by the standard definitions of CHF and ACS by the AHA)?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input type="checkbox"/> Not Available



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<b>PACE Screening Form</b>			
17) Does the patient have known HIV positive or have active HBV or HCV disease?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input type="checkbox"/> Not Available
18) Does the patient have a history of cancer within the last 5 years, except basal cell skin carcinoma?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input type="checkbox"/> Not Available
19) Does the patient have any bleeding diathesis defined as INR $\geq$ 2.0 (off anticoagulation therapy) or history of platelet count less than 100,000 or hemophilia?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input type="checkbox"/> Not Available
20) Does the patient have a contraindication to MRI (including knee/tibial/fibular replacement hardware in the index leg) or a known allergy to MR contrast media?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input type="checkbox"/> Not Available
21) Does the patient have chronic kidney disease (eGFR $<$ 30 by MDRD or Mayo or Cockcroft-Gault formula)?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input type="checkbox"/> Not Available
22) Does the patient have uncontrolled diabetes (HbA1C $>$ 8.5)?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input type="checkbox"/> Not Available
23) Is the patient planning a change (initiation or termination) to active involvement in a supervised exercise program during study participation?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input type="checkbox"/> Not Available
24) Is the patient planning to change PAD medical therapy during the duration of the study?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input type="checkbox"/> Not Available
25) Is the patient unable to provide written informed consent due to cognitive or language barriers?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input type="checkbox"/> Not Available
26) Is the patient enrolled in another clinical investigative trial?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input type="checkbox"/> Not Available
27) Does the patient have any condition requiring immunosuppressant medications?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input type="checkbox"/> Not Available
28) Does the patient have a history of inflammatory or progressively fibrotic conditions?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input type="checkbox"/> Not Available
29) Does the patient have a patent infrainguinal bypass graft in the index limb, with or without evidence of a hemodynamically significant stenosis or other defect (kinking, pseudoaneurysm, or fistula)? Note: Patients with an occluded infrainguinal bypass graft or a patent aortobifemoral or femoral-femoral bypass graft are NOT excluded.	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input type="checkbox"/> Not Available
30) Does the patient have myelodysplastic syndrome (MDS)?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input type="checkbox"/> Not Available



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Date source form completed (mm/dd/yyyy): ____ / ____ / ____			
<b>PACE Screening Form</b>			
31) Does the patient have any untreated stenosis > 70% of the distal aorta, common iliac, or external iliac arteries by CT, Angiography or MRI imaging?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input type="checkbox"/> Not Available
32) Is there presence of any clinical condition that in the opinion of the PI makes the patient not suitable to participate in this trial?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input type="checkbox"/> Not Available
Comments			

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# Cardiovascular Cell Therapy Research Network

## PACE Protocol Workbook

FORM NO. CND002	
Study ID:	
Acrostic Identifier (if applicable):	
Date source form completed (mm/dd/yyyy): ____/____/____	
<b>Demographics</b>	
Last Name:	
First Name:	
Middle Initial:	
Has the participant signed the consent form? Y <input type="checkbox"/> N <input type="checkbox"/> If yes, Date of Consent: (mm/dd/yyyy) ____/____/____  If no, please check a reason below: <input type="checkbox"/> Declined <input type="checkbox"/> Does not want placebo <input type="checkbox"/> Could not decide <input type="checkbox"/> Too far / Transportation issues <input type="checkbox"/> Family issues or concerns <input type="checkbox"/> Unwilling to participate in study procedures and/or follow-up <input type="checkbox"/> Too busy / Too much going on <input type="checkbox"/> Other (please specify): _____	<u>Biorepository Consents signed:</u> Samples for future research Y <input type="checkbox"/> N <input type="checkbox"/> Samples for genetic research Y <input type="checkbox"/> N <input type="checkbox"/> Inclusion of de-identified information Y <input type="checkbox"/> N <input type="checkbox"/>
Agreed to be contacted for future trial opportunities: Y <input type="checkbox"/> N <input type="checkbox"/> N/A (IRB does not allow) <input type="checkbox"/>	
Date of Birth: (mm/dd/yyyy) ____/____/____	
Gender M <input type="checkbox"/> F <input type="checkbox"/>	
Hispanic, Latino, or Spanish Origin Y <input type="checkbox"/> N <input type="checkbox"/> No response <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"/> No response <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"/> No response <input type="checkbox"/>	



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FORM NO. CND002	
Study ID:	
Acrostic Identifier (if applicable):	
Date source form completed (mm/dd/yyyy): ____ / ____ / ____	
<b>Demographics</b>	
Highest Education Level (choose one):	
Unknown	<input type="checkbox"/>
Some schooling (no diploma)	<input type="checkbox"/>
High School Diploma or GED	<input type="checkbox"/>
Some college or Associate's Degree (2 years)	<input type="checkbox"/>
Bachelor's Degree (4 years)	<input type="checkbox"/>
Master's Degree	<input type="checkbox"/>
Doctorate Degree	<input type="checkbox"/>
Professional Degree (MD, DDS, DVM, JD, etc.)	<input type="checkbox"/>
No response	<input type="checkbox"/>
Comments	

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FORM NO. CND003		
Acrostic Identifier:		
Study ID:		
Date source form completed (mm/dd/yyyy): ____/____/____		
Eligibility Criteria		
Y	N	Inclusion Criteria (Must answer Yes to either the first or second question AND Yes to all remaining questions to be eligible)
<input type="checkbox"/>	<input type="checkbox"/>	Patient has atherosclerotic PAD with classic claudication (exercise induced pain, cramps, fatigue, or other equivalent discomfort involving large muscle groups of the leg(s) that is consistently relieved by rest) as defined by the San Diego Claudication Questionnaire.
<input type="checkbox"/>	<input type="checkbox"/>	Patient has atypical leg pain (exertional leg pain that does not begin at rest or does not resolve consistently with rest) as defined by the San Diego Claudication Questionnaire.
<input type="checkbox"/>	<input type="checkbox"/>	Patient is at least 40 years of age.
<input type="checkbox"/>	<input type="checkbox"/>	Patient has a resting ankle-brachial index of less than 0.90 or a resting toe-brachial index of less than 0.70 at baseline testing.
<input type="checkbox"/>	<input type="checkbox"/>	Patient has significant stenosis or occlusion of infrainguinal arteries including the superficial femoral artery, popliteal artery and/or infrapopliteal arteries determined by: Duplex ultrasound imaging, or lower extremity CTA, or lower extremity MRA, or lower extremity catheter-based contrast arteriography.
Y	N	Exclusion Criteria (Must answer No to all questions to be eligible)
<input type="checkbox"/>	<input type="checkbox"/>	Presence of any musculoskeletal disease, cardiac or pulmonary disease, or neurological disease that limits the patient's ability to walk to fulfill protocol requirements (claudication must be the consistent primary exercise limitation).
<input type="checkbox"/>	<input type="checkbox"/>	Inability to complete treadmill testing per protocol requirements.
<input type="checkbox"/>	<input type="checkbox"/>	Ability to walk for more than 12 minutes on the treadmill during treadmill testing.
<input type="checkbox"/>	<input type="checkbox"/>	Identified both legs as equivocally symptomatic or alternated between symptomatic legs on the baseline treadmill tests.
<input type="checkbox"/>	<input type="checkbox"/>	Critical limb ischemia (Rutherford classes 4 or 5).
<input type="checkbox"/>	<input type="checkbox"/>	Recent (< 3 months) infrainguinal revascularization (surgery or endovascular revascularization) or planned during study period.
<input type="checkbox"/>	<input type="checkbox"/>	Peripheral pitting edema >2+.
<input type="checkbox"/>	<input type="checkbox"/>	Pregnant, planning to become pregnant in the next 12 months, or lactating status.
<input type="checkbox"/>	<input type="checkbox"/>	CHF hospitalization within the last 1 month prior to enrollment (as defined by the standard definitions of CHF and ACS by the AHA).
<input type="checkbox"/>	<input type="checkbox"/>	Acute coronary syndrome in the last 1 month prior to enrollment (as defined by the standard definitions of CHF and ACS by the AHA).
<input type="checkbox"/>	<input type="checkbox"/>	HIV positive or active HBV or HCV disease.
<input type="checkbox"/>	<input type="checkbox"/>	History of cancer within the last 5 years, except basal cell skin carcinoma.
<input type="checkbox"/>	<input type="checkbox"/>	Any bleeding diathesis defined as an INR $\geq$ 2.0 (off anticoagulation therapy) or history of platelet count less than 100,000 or hemophilia.
<input type="checkbox"/>	<input type="checkbox"/>	Contraindication to MRI (including knee/tibial/fibular replacement hardware in the index leg) or known allergy to MR contrast media.
<input type="checkbox"/>	<input type="checkbox"/>	Chronic kidney disease (eGFR < 30 by MDRD or Mayo or Cockcroft-Gault formula).
<input type="checkbox"/>	<input type="checkbox"/>	Uncontrolled diabetes (HbA1C >8.5).



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<b>FORM NO. CND003</b>		
Acrostic Identifier:		
Study ID:		
Date source form completed (mm/dd/yyyy): ____/____/____		
<b>Eligibility Criteria</b>		
<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"/>	Planned change (initiate or terminate) to active involvement in a supervised exercise program during study participation.
<input type="checkbox"/>	<input type="checkbox"/>	Plans to change PAD medical therapy during the duration of the study.
<input type="checkbox"/>	<input type="checkbox"/>	Unable to provide written informed consent due to cognitive or language barriers.
<input type="checkbox"/>	<input type="checkbox"/>	Enrolled in another clinical investigative trial.
<input type="checkbox"/>	<input type="checkbox"/>	Any condition requiring immunosuppressant medications.
<input type="checkbox"/>	<input type="checkbox"/>	History of inflammatory or progressively fibrotic conditions.
<input type="checkbox"/>	<input type="checkbox"/>	Has a patent infrainguinal bypass graft in the index limb, with or without evidence of a hemodynamically significant stenosis or other defect (kinking, pseudoaneurysm, or fistula). Note: Patients with an occluded infrainguinal bypass graft or a patent aortobifemoral or femoral-femoral bypass graft are NOT excluded.
<input type="checkbox"/>	<input type="checkbox"/>	Myelodysplastic syndrome (MDS).
<input type="checkbox"/>	<input type="checkbox"/>	Any untreated stenosis > 70% of the distal aorta, common iliac, or external iliac arteries by CT, Angiography or MRI imaging.
<input type="checkbox"/>	<input type="checkbox"/>	Any other clinical condition that in the opinion of the PI makes the patient not suitable to participate in this trial.
<input type="checkbox"/>	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.	
Comments:		
<input type="checkbox"/> PI reviewed Eligibility Criteria worksheet <span style="float: right;">Date PI reviewed (mm/dd/yyyy): ____/____/____</span>		

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

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

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## PACE Protocol Workbook

FORM NO. CND004						
Acrostic Identifier:						
Study ID:						
Date source form completed (mm/dd/yyyy): ____/____/____						
<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"/>		Neither <input type="checkbox"/>			
	Insulin <input type="checkbox"/>		Both <input type="checkbox"/>			
<b>Hypertension</b>	No <input type="checkbox"/>	Yes <input type="checkbox"/>				
<u>Hypertension Treatment:</u>	No medication <input type="checkbox"/>					
	1 medication <input type="checkbox"/>					
	2 or more medications <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>Smoking</b>	Never <input type="checkbox"/>	Previous <input type="checkbox"/>	Current <input type="checkbox"/>			
	Yr stopped: ____		packs/day: ____			
<b>Comorbidities</b>						
<b>History of cancer</b>	No <input type="checkbox"/>	Yes <input type="checkbox"/>	Unknown <input type="checkbox"/>			
(If <5 years, patient is excluded unless basal cell carcinoma)			If yes, type of cancer: _____			
			Date of diagnosis: ____/____/____			
<b>History of renal insufficiency</b>	No <input type="checkbox"/>	Yes <input type="checkbox"/>	Unknown <input type="checkbox"/>			
If yes, is the patient on dialysis?	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>History of TIAs</b>	No <input type="checkbox"/>	Yes <input type="checkbox"/>				
<b>History of stroke</b>	No <input type="checkbox"/>	Current Deficit <input type="checkbox"/>	Completely Resolved <input type="checkbox"/>			
<b>History of aneurysm</b>	No <input type="checkbox"/>	Yes <input type="checkbox"/>				
<b>Obese</b>	No <input type="checkbox"/>	Yes <input type="checkbox"/>				
<b>PAD History</b>						
Prior to this visit, have you undergone treatment for:				Left Leg	Right Leg	If yes, most recent date
Lower extremity revascularization -- open surgical (bypass)	No <input type="checkbox"/>	Yes <input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	____/____/____
Lower extremity revascularization -- open surgical (endarterectomy)	No <input type="checkbox"/>	Yes <input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	____/____/____
Lower extremity revascularization -- endovascular	No <input type="checkbox"/>	Yes <input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	____/____/____
History of claudication	No <input type="checkbox"/>	Yes <input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	



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FORM NO. CND004							
Acrostic Identifier:							
Study ID:							
Date source form completed (mm/dd/yyyy): ____/____/____							
<b>Baseline Risk Factors</b>							
<b>Describe Other Revascularization Procedures:</b>							
1.							
2.							
3.							
4.							
5.							
<b>Other Cardiac History</b>							
Prior to this visit, have you undergone treatment for:							
Congestive heart failure	No	<input type="checkbox"/>	Yes	<input type="checkbox"/>			
PCI	No	<input type="checkbox"/>	Yes	<input type="checkbox"/>			
Previous MI	No	<input type="checkbox"/>	Yes	<input type="checkbox"/>			
Bypass surgery	No	<input type="checkbox"/>	Yes	<input type="checkbox"/>			
Cardiac catheterization	No	<input type="checkbox"/>	Yes	<input type="checkbox"/>			
Carotid endarterectomy/angioplasty	No	<input type="checkbox"/>	Yes	<input type="checkbox"/>			
Cardiac pacemaker	No	<input type="checkbox"/>	Yes	<input type="checkbox"/>			
Valvular heart disease	No	<input type="checkbox"/>	Yes	<input type="checkbox"/>			
If yes, check all that apply:			mitral	<input type="checkbox"/>			
			aortic	<input type="checkbox"/>			
			pulmonic	<input type="checkbox"/>			
			tricuspid	<input type="checkbox"/>			
Other cardiovascular interventions	No	<input type="checkbox"/>	Yes	<input type="checkbox"/>			
If yes, please describe other coronary interventions:							
<b>Procedure:</b>							
1.							
2.							
3.							
4.							
5.							
<b>Questions:</b>							
If female, are you of child bearing potential?		No	<input type="checkbox"/>	Yes	<input type="checkbox"/>	N/A	<input type="checkbox"/>
		If no, check one: post menopausal			<input type="checkbox"/>	surgically sterile	<input type="checkbox"/>
Comments:							

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FORM NO. CND005					
Acrostic Identifier:					
Study ID:					
Date source form completed (mm/dd/yyyy): ____/____/____					
<b>Physical Exam - Baseline</b>					
Date of Exam: ____/____/____					
<input type="checkbox"/> Check this box if re-consent was required					
Date patient reconsented: ____/____/____		Consent version: _____			
<b>Vital Signs</b>		<b>Rutherford Category:</b>		<b>Fontaine Classification:</b>	
Height: _____	<input type="checkbox"/> inches <input type="checkbox"/> cm	0 <input type="checkbox"/>	}	Eligible	Stage 1 <input type="checkbox"/>
Weight: _____	<input type="checkbox"/> pounds <input type="checkbox"/> kg	1 <input type="checkbox"/>			Stage 2a <input type="checkbox"/>
Temperature: _____.____°F	<input type="checkbox"/> oral <input type="checkbox"/> auricle	2 <input type="checkbox"/>			Stage 2b <input type="checkbox"/>
Respirations: ____ breaths/minute		3 <input type="checkbox"/>			Stage 3 <input type="checkbox"/>
Heart rate: ____ beats/minute		4 <input type="checkbox"/>	}	Ineligible	Stage 4 <input type="checkbox"/>
Blood Pressure: _____ / _____ mmHg (supine)	SBP      DBP	5 <input type="checkbox"/>			
		6 <input type="checkbox"/>			
<u>Rutherford Categories:</u> 0=asymptomatic; 1=mild claudication; 2=moderate claudication; 3=severe claudication; 4=ischemic rest pain; 5=minor tissue loss; 6=Ulceration or gangrene					
<u>Fontaine Classification:</u> 1=no symptoms; 2a=intermittent claudication w/o pain on resting, but with claudication at a distance of >200 meters; 2b=intermittent claudication w/o pain on resting, but with a claudication distance of <200 meters; 3=nocturnal and/or resting pain; 4=necrosis (death of tissue) and/or gangrene in the limb.					
<b>PAD Treatment:</b>					
Have you participated in a supervised exercise program (e.g. with a trainer, exercise protocol or rehabilitation program) for at least 2 weeks within the last six weeks or are planning to join a program during the study period? (If yes, <b>patient is excluded</b> )					Yes <input type="checkbox"/> No <input type="checkbox"/>
Have you changed medical therapy for PAD within the last four weeks? (If yes, please describe changes in comments -- <b>patient is excluded</b> )					Yes <input type="checkbox"/> No <input type="checkbox"/>
<b>Exam: If "Abnormal" is checked, please "Describe" the condition and also check if "Clinically Significant"</b>					
Organs	Not Examined	Normal	Abnormal	Clinically Significant	Describe
Skin	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
HEENT	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Lungs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Heart	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Abdomen	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Lymph Nodes	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Musculoskeletal	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Neurological	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Other: _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	



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FORM NO. CND005			
Acrostic Identifier:			
Study ID:			
Date source form completed (mm/dd/yyyy): ____/____/____			
<b>Physical Exam - Baseline</b>			
<b>Vascular Exam</b>			
<b>Pulses:</b>	Left		Right
Carotid	Bounding (3+) <input type="checkbox"/>	Normal (2+) <input type="checkbox"/>	Bounding (3+) <input type="checkbox"/> Normal (2+) <input type="checkbox"/> Diminished (1+) <input type="checkbox"/> Absent (0) <input type="checkbox"/>
Femoral	Bounding (3+) <input type="checkbox"/>	Normal (2+) <input type="checkbox"/>	Bounding (3+) <input type="checkbox"/> Normal (2+) <input type="checkbox"/> Diminished (1+) <input type="checkbox"/> Absent (0) <input type="checkbox"/>
Popliteal	Bounding (3+) <input type="checkbox"/>	Normal (2+) <input type="checkbox"/>	Bounding (3+) <input type="checkbox"/> Normal (2+) <input type="checkbox"/> Diminished (1+) <input type="checkbox"/> Absent (0) <input type="checkbox"/>
Posterior Tibial (PT)	Bounding (3+) <input type="checkbox"/>	Normal (2+) <input type="checkbox"/>	Bounding (3+) <input type="checkbox"/> Normal (2+) <input type="checkbox"/> Diminished (1+) <input type="checkbox"/> Absent (0) <input type="checkbox"/>
Dorsalis Pedis (DP)	Bounding (3+) <input type="checkbox"/>	Normal (2+) <input type="checkbox"/>	Bounding (3+) <input type="checkbox"/> Normal (2+) <input type="checkbox"/> Diminished (1+) <input type="checkbox"/> Absent (0) <input type="checkbox"/>
<b>PAD Symptoms and Signs:</b>	Left Leg		Right Leg
Skin ulcers?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>
Gangrene?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>
Ischemic rest pain?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>
Pitting Edema (If 3+ is checked, patient is excluded)	3+ <input type="checkbox"/>	2+ <input type="checkbox"/>	3+ <input type="checkbox"/> 2+ <input type="checkbox"/> 1+ <input type="checkbox"/> None <input type="checkbox"/>
<b>Questions</b>			
Has the patient experienced any reportable (grade 2 or higher) adverse events since consent signed? (If yes, complete AE form)			Yes <input type="checkbox"/> No <input type="checkbox"/>
Has the patient completed the San Diego Claudication Questionnaire? (If no, please explain in Comments)			Yes <input type="checkbox"/> No <input type="checkbox"/>
Has the patient completed Quality of Life Questionnaires (WIQ, PAQ, and Patient Expectaion Survey)? (If no, please explain in Comments)			Yes <input type="checkbox"/> No <input type="checkbox"/>
Was the Infectious Disease lab panel drawn and sent for analysis? (If no, please enter a reason in Comments)			Yes <input type="checkbox"/> No <input type="checkbox"/>
Was the Treadmill Test with pre & post ABIs, COT and PWT completed to send to the Core Lab? (If no, please explain in Comments)			Yes <input type="checkbox"/> No <input type="checkbox"/>
Was the MRI completed to send to the Core Lab? (If no, please explain in Comments)			Yes <input type="checkbox"/> No <input type="checkbox"/>
Comments:			

MD Signature \_\_\_\_\_ Date: \_\_\_\_\_

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



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

FORM NO. CND005

Acrostic Identifier: \_\_\_\_\_

Study ID: \_\_\_\_\_

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

**Physical Exam - FollowUp (BMA)**

Date of Exam: \_\_\_\_/\_\_\_\_/\_\_\_\_  Visit is outside time window Reason: \_\_\_\_\_

Check this box if re-consent was required Visit Type: \_\_\_\_\_

Date patient reconsented: \_\_\_\_/\_\_\_\_/\_\_\_\_ Consent version: \_\_\_\_\_

**Vital Signs**

Weight: _____	<input type="checkbox"/> pounds	<input type="checkbox"/> kg
Temperature: _____.____°F	<input type="checkbox"/> oral	<input type="checkbox"/> auricle
Respirations: ____ breaths/minute		
Heart rate: ____ beats/minute		
Blood Pressure: _____ / _____ mmHg (supine)		
SBP	DBP	

**Exam: If "Abnormal" is checked, please "Describe" the condition and also check if "Clinically Significant"**

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

Organs	Not Examined	Normal	Abnormal	Clinically Significant	Describe
Skin	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
HEENT	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Lungs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Heart	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Abdomen	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Lymph Nodes	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Musculoskeletal	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Neurological	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Other: _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

**Vascular Exam**

Pulses:	Left	Right
Carotid	Bounding (3+) <input type="checkbox"/>	Bounding (3+) <input type="checkbox"/>
	Normal (2+) <input type="checkbox"/>	Normal (2+) <input type="checkbox"/>
	Diminished (1+) <input type="checkbox"/>	Diminished (1+) <input type="checkbox"/>
	Absent (0) <input type="checkbox"/>	Absent (0) <input type="checkbox"/>
Femoral	Bounding (3+) <input type="checkbox"/>	Bounding (3+) <input type="checkbox"/>
	Normal (2+) <input type="checkbox"/>	Normal (2+) <input type="checkbox"/>
	Diminished (1+) <input type="checkbox"/>	Diminished (1+) <input type="checkbox"/>
	Absent (0) <input type="checkbox"/>	Absent (0) <input type="checkbox"/>



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

<b>FORM NO. CND005</b>			
Acrostic Identifier:			
Study ID:			
Date source form completed: ____/____/____			
<b>Physical Exam - FollowUp (BMA)</b>			
<b>Vascular Exam</b>			
<b>Pulses:</b>	<b>Left</b>		<b>Right</b>
Popliteal	Bounding (3+) <input type="checkbox"/>	Normal (2+) <input type="checkbox"/>	Bounding (3+) <input type="checkbox"/>
	Diminished (1+) <input type="checkbox"/>	Absent ( 0 ) <input type="checkbox"/>	Normal (2+) <input type="checkbox"/>
			Diminished (1+) <input type="checkbox"/>
			Absent ( 0 ) <input type="checkbox"/>
Posterior Tibial (PT)	Bounding (3+) <input type="checkbox"/>	Normal (2+) <input type="checkbox"/>	Bounding (3+) <input type="checkbox"/>
	Diminished (1+) <input type="checkbox"/>	Absent ( 0 ) <input type="checkbox"/>	Normal (2+) <input type="checkbox"/>
			Diminished (1+) <input type="checkbox"/>
			Absent ( 0 ) <input type="checkbox"/>
Dorsalis Pedis (DP)	Bounding (3+) <input type="checkbox"/>	Normal (2+) <input type="checkbox"/>	Bounding (3+) <input type="checkbox"/>
	Diminished (1+) <input type="checkbox"/>	Absent ( 0 ) <input type="checkbox"/>	Normal (2+) <input type="checkbox"/>
			Diminished (1+) <input type="checkbox"/>
			Absent ( 0 ) <input type="checkbox"/>
<b>PAD Symptoms and Signs:</b>	<b>Left Leg</b>		<b>Right Leg</b>
Skin ulcers?	Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>
Gangrene?	Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>
Ischemic rest pain?	Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>
Pitting Edema (If 3+ is checked, patient is excluded)	3+ <input type="checkbox"/>	2+ <input type="checkbox"/>	3+ <input type="checkbox"/>
	1+ <input type="checkbox"/>	None <input type="checkbox"/>	2+ <input type="checkbox"/>
			1+ <input type="checkbox"/>
			None <input type="checkbox"/>
<b>Questions</b>			
Has the patient experienced any reportable (grade 2 or higher) adverse events since the last visit? (If yes, complete AE form)			Yes <input type="checkbox"/> No <input type="checkbox"/>
Have there been any changes to medications since last visit? (If yes, update medication form)			Yes <input type="checkbox"/> No <input type="checkbox"/>
Has the patient completed Quality of Life Questionnaires (WIQ & PAQ Survey)? (If no, please explain in Comments)			Yes <input type="checkbox"/> No <input type="checkbox"/>
Was the Treadmill Test with pre & post ABIs, COT and PWT completed to send to the Core Lab? (If no, please explain in Comments)			Yes <input type="checkbox"/> No <input type="checkbox"/>
What is your smoking status?		Never <input type="checkbox"/>	Previous <input type="checkbox"/>
			Current <input type="checkbox"/>
			Yr stopped: ____ packs/day: ____
Were one 3 ml, one 4 ml and one 10 ml purple top tubes of peripheral blood drawn to ship to the biorepository for FACS analysis and a second 3 ml purple top tube of peripheral blood drawn for plasma and buffy coat collection ? (If no, please explain in the Comments)			Yes <input type="checkbox"/> No <input type="checkbox"/>
<b>Verify patient consented to Biorepository before you draw Biorepository bloods.</b>			
Comments:			

MD Signature \_\_\_\_\_ Date: \_\_\_\_\_

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



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

FORM NO. CND005						
Acrostic Identifier:						
Study ID:						
Date source form completed (mm/dd/yyyy): ____/____/____						
<b>Physical Exam - FollowUp (SPI, Wk1)</b>						
Date of Exam: ____/____/____		<input type="checkbox"/> Visit is outside time window		Reason:		
<input type="checkbox"/> Check this box if re-consent was required					Visit Type:	
Date patient reconsented: ____/____/____		Consent version:				
<b>Vital Signs</b>			<b>Infection Assessment</b>	<b>BMA</b>		<b>SPI</b>
				<i>Left Iliac Crest Site</i>	<i>Right Iliac Crest Site</i>	<i>Injection Sites</i>
Weight: _____ <input type="checkbox"/> pounds <input type="checkbox"/> kg		Erythema	Y <input type="checkbox"/> N <input type="checkbox"/>	Y <input type="checkbox"/> N <input type="checkbox"/>	Y <input type="checkbox"/> N <input type="checkbox"/>	
Temperature: _____. ____ °F <input type="checkbox"/> oral <input type="checkbox"/> auricle		Hematoma	Y <input type="checkbox"/> N <input type="checkbox"/>	Y <input type="checkbox"/> N <input type="checkbox"/>	Y <input type="checkbox"/> N <input type="checkbox"/>	
Respirations: ____ breaths/minute		Pain	Y <input type="checkbox"/> N <input type="checkbox"/>	Y <input type="checkbox"/> N <input type="checkbox"/>	Y <input type="checkbox"/> N <input type="checkbox"/>	
Heart rate: ____ beats/minute		Comments (If Yes to any above; also complete an AE form if grade 2 or higher)				
Blood Pressure: _____ / _____ mmHg (supine) SBP                      DBP						
<b>Exam: If "Abnormal" is checked, please "Describe" the condition and also check if "Clinically Significant"</b>						
Have changes occurred since previous visit?    Yes <input type="checkbox"/> No <input type="checkbox"/> If no, table is complete.						
<i>Organs</i>	<i>Not Examined</i>	<i>Normal</i>	<i>Abnormal</i>	<i>Clinically Significant</i>	<i>Describe</i>	
Skin	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
HEENT	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Lungs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Heart	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Abdomen	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Lymph Nodes	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Musculoskeletal	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Neurological	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Other: _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
<b>Vascular Exam</b>						
<b>Pulses:</b>		<b>Left</b>		<b>Right</b>		
Carotid		Bounding (3+) <input type="checkbox"/>		Bounding (3+) <input type="checkbox"/>		
		Normal (2+) <input type="checkbox"/>		Normal (2+) <input type="checkbox"/>		
		Diminished (1+) <input type="checkbox"/>		Diminished (1+) <input type="checkbox"/>		
		Absent ( 0 ) <input type="checkbox"/>		Absent ( 0 ) <input type="checkbox"/>		



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

FORM NO. CND005			
Acrostic Identifier:			
Study ID:			
Date source form completed (mm/dd/yyyy): ____/____/____			
<b>Physical Exam - FollowUp (SPI, Wk1)</b>			
<b>Vascular Exam</b>			
<b>Pulses:</b>	<b>Left</b>		<b>Right</b>
Femoral	Bounding (3+) <input type="checkbox"/>	Bounding (3+) <input type="checkbox"/>	Bounding (3+) <input type="checkbox"/>
	Normal (2+) <input type="checkbox"/>	Normal (2+) <input type="checkbox"/>	Normal (2+) <input type="checkbox"/>
	Diminished (1+) <input type="checkbox"/>	Diminished (1+) <input type="checkbox"/>	Diminished (1+) <input type="checkbox"/>
	Absent (0) <input type="checkbox"/>	Absent (0) <input type="checkbox"/>	Absent (0) <input type="checkbox"/>
Popliteal	Bounding (3+) <input type="checkbox"/>	Bounding (3+) <input type="checkbox"/>	Bounding (3+) <input type="checkbox"/>
	Normal (2+) <input type="checkbox"/>	Normal (2+) <input type="checkbox"/>	Normal (2+) <input type="checkbox"/>
	Diminished (1+) <input type="checkbox"/>	Diminished (1+) <input type="checkbox"/>	Diminished (1+) <input type="checkbox"/>
	Absent (0) <input type="checkbox"/>	Absent (0) <input type="checkbox"/>	Absent (0) <input type="checkbox"/>
Posterior Tibial (PT)	Bounding (3+) <input type="checkbox"/>	Bounding (3+) <input type="checkbox"/>	Bounding (3+) <input type="checkbox"/>
	Normal (2+) <input type="checkbox"/>	Normal (2+) <input type="checkbox"/>	Normal (2+) <input type="checkbox"/>
	Diminished (1+) <input type="checkbox"/>	Diminished (1+) <input type="checkbox"/>	Diminished (1+) <input type="checkbox"/>
	Absent (0) <input type="checkbox"/>	Absent (0) <input type="checkbox"/>	Absent (0) <input type="checkbox"/>
Dorsalis Pedis (DP)	Bounding (3+) <input type="checkbox"/>	Bounding (3+) <input type="checkbox"/>	Bounding (3+) <input type="checkbox"/>
	Normal (2+) <input type="checkbox"/>	Normal (2+) <input type="checkbox"/>	Normal (2+) <input type="checkbox"/>
	Diminished (1+) <input type="checkbox"/>	Diminished (1+) <input type="checkbox"/>	Diminished (1+) <input type="checkbox"/>
	Absent (0) <input type="checkbox"/>	Absent (0) <input type="checkbox"/>	Absent (0) <input type="checkbox"/>
<b>PAD Symptoms and Signs:</b>	<b>Left Leg</b>		<b>Right Leg</b>
Skin ulcers?	Yes <input type="checkbox"/> No <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>
Gangrene?	Yes <input type="checkbox"/> No <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>
Ischemic rest pain?	Yes <input type="checkbox"/> No <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>
Pitting Edema (If 3+ is checked, patient is excluded)	3+ <input type="checkbox"/>	3+ <input type="checkbox"/>	3+ <input type="checkbox"/>
	2+ <input type="checkbox"/>	2+ <input type="checkbox"/>	2+ <input type="checkbox"/>
	1+ <input type="checkbox"/>	1+ <input type="checkbox"/>	1+ <input type="checkbox"/>
	None <input type="checkbox"/>	None <input type="checkbox"/>	None <input type="checkbox"/>
<b>Questions</b>			
Has the patient experienced any reportable (grade 2 or higher) adverse events since the last visit? (If yes, complete AE form)			Yes <input type="checkbox"/> No <input type="checkbox"/>
Have there been any changes to medications since last visit? (If yes, update medication form)			Yes <input type="checkbox"/> No <input type="checkbox"/>
Were one 3 ml, one 4 ml and one 10 ml purple top tubes of peripheral blood drawn to ship to the biorepository for FACS analysis and a second 3 ml purple top tube of peripheral blood drawn for plasma and buffy coat collection ? (If no, please explain in the Comments)			Yes <input type="checkbox"/> No <input type="checkbox"/>
<b>Verify patient consented to Biorepository before you draw Biorepository bloods.</b>			
Comments:			

MD Signature \_\_\_\_\_ Date: \_\_\_\_\_

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





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

FORM NO. CND005

Acrostic Identifier: \_\_\_\_\_

Study ID: \_\_\_\_\_

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

**Physical Exam - FollowUp ( M1)**

Date of Exam: \_\_\_\_/\_\_\_\_/\_\_\_\_  Visit is outside time window Reason: \_\_\_\_\_

Check this box if re-consent was required Visit Type: \_\_\_\_\_

Date patient reconsented: \_\_\_\_/\_\_\_\_/\_\_\_\_ Consent version: \_\_\_\_\_

Vital Signs	
Weight: _____	<input type="checkbox"/> pounds <input type="checkbox"/> kg
Temperature: _____.____°F	<input type="checkbox"/> oral <input type="checkbox"/> auricle
Respirations: ____ breaths/minute	
Heart rate: ____ beats/minute	
Blood Pressure: _____ / _____ mmHg (supine)	
SBP	DBP

**Exam: If "Abnormal" is checked, please "Describe" the condition and also check if "Clinically Significant"**

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

Organs	Not Examined	Normal	Abnormal	Clinically Significant	Describe
Skin	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
HEENT	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Lungs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Heart	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Abdomen	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Lymph Nodes	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Musculoskeletal	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Neurological	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Other: _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

**Vascular Exam**

Pulses:	Left	Right
Carotid	Bounding (3+) <input type="checkbox"/>	Bounding (3+) <input type="checkbox"/>
	Normal (2+) <input type="checkbox"/>	Normal (2+) <input type="checkbox"/>
	Diminished (1+) <input type="checkbox"/>	Diminished (1+) <input type="checkbox"/>
	Absent ( 0 ) <input type="checkbox"/>	Absent ( 0 ) <input type="checkbox"/>
Femoral	Bounding (3+) <input type="checkbox"/>	Bounding (3+) <input type="checkbox"/>
	Normal (2+) <input type="checkbox"/>	Normal (2+) <input type="checkbox"/>
	Diminished (1+) <input type="checkbox"/>	Diminished (1+) <input type="checkbox"/>
	Absent ( 0 ) <input type="checkbox"/>	Absent ( 0 ) <input type="checkbox"/>



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

<b>FORM NO. CND005</b>			
Acrostic Identifier:			
Study ID:			
Date source form completed: ____/____/____			
<b>Physical Exam - FollowUp ( M1)</b>			
<b>Vascular Exam</b>			
<b>Pulses:</b>	<b>Left</b>		<b>Right</b>
Popliteal	Bounding (3+) <input type="checkbox"/>	Normal (2+) <input type="checkbox"/>	Bounding (3+) <input type="checkbox"/>
	Diminished (1+) <input type="checkbox"/>	Absent ( 0 ) <input type="checkbox"/>	Normal (2+) <input type="checkbox"/>
			Diminished (1+) <input type="checkbox"/>
			Absent ( 0 ) <input type="checkbox"/>
Posterior Tibial (PT)	Bounding (3+) <input type="checkbox"/>	Normal (2+) <input type="checkbox"/>	Bounding (3+) <input type="checkbox"/>
	Diminished (1+) <input type="checkbox"/>	Absent ( 0 ) <input type="checkbox"/>	Normal (2+) <input type="checkbox"/>
			Diminished (1+) <input type="checkbox"/>
			Absent ( 0 ) <input type="checkbox"/>
Dorsalis Pedis (DP)	Bounding (3+) <input type="checkbox"/>	Normal (2+) <input type="checkbox"/>	Bounding (3+) <input type="checkbox"/>
	Diminished (1+) <input type="checkbox"/>	Absent ( 0 ) <input type="checkbox"/>	Normal (2+) <input type="checkbox"/>
			Diminished (1+) <input type="checkbox"/>
			Absent ( 0 ) <input type="checkbox"/>
<b>PAD Symptoms and Signs:</b>	<b>Left Leg</b>		<b>Right Leg</b>
Skin ulcers?	Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>
Gangrene?	Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>
Ischemic rest pain?	Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>
Pitting Edema (If 3+ is checked, patient is excluded)	3+ <input type="checkbox"/>	2+ <input type="checkbox"/>	3+ <input type="checkbox"/>
	1+ <input type="checkbox"/>	None <input type="checkbox"/>	2+ <input type="checkbox"/>
			1+ <input type="checkbox"/>
			None <input type="checkbox"/>
<b>Questions</b>			
Has the patient experienced any reportable (grade 2 or higher) adverse events since the last visit? (If yes, complete AE form)			Yes <input type="checkbox"/> No <input type="checkbox"/>
Have there been any changes to medications since last visit? (If yes, update medication form)			Yes <input type="checkbox"/> No <input type="checkbox"/>
Has the patient completed Quality of Life Questionnaires (WIQ & PAQ Survey)? (If no, please explain in Comments)			Yes <input type="checkbox"/> No <input type="checkbox"/>
What is your smoking status?		Never <input type="checkbox"/>	Previous <input type="checkbox"/>
			Current <input type="checkbox"/>
			Yr stopped: ____ packs/day: ____
Were one 3 ml, one 4 ml and one 10 ml purple top tubes of peripheral blood drawn to ship to the biorepository for FACS analysis and a second 3 ml purple top tube of peripheral blood drawn for plasma and buffy coat collection ? (If no, please explain in the Comments)			Yes <input type="checkbox"/> No <input type="checkbox"/>
<b>Verify patient consented to Biorepository before you draw Biorepository bloods.</b>			
Comments:			

MD Signature \_\_\_\_\_ Date: \_\_\_\_\_

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



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

FORM NO. CND005

Acrostic Identifier: \_\_\_\_\_

Study ID: \_\_\_\_\_

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

**Physical Exam - FollowUp (M3, Interim)**

Date of Exam: \_\_\_\_/\_\_\_\_/\_\_\_\_  Visit is outside time window Reason: \_\_\_\_\_

Check this box if re-consent was required Visit Type: \_\_\_\_\_

Date patient reconsented: \_\_\_\_/\_\_\_\_/\_\_\_\_ Consent version: \_\_\_\_\_

Vital Signs	
Weight: _____	<input type="checkbox"/> pounds <input type="checkbox"/> kg
Temperature: _____.____°F	<input type="checkbox"/> oral <input type="checkbox"/> auricle
Respirations: ____ breaths/minute	
Heart rate: ____ beats/minute	
Blood Pressure: _____ / _____ mmHg (supine)	
SBP	DBP

**Exam: If "Abnormal" is checked, please "Describe" the condition and also check if "Clinically Significant"**

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

Organs	Not Examined	Normal	Abnormal	Clinically Significant	Describe
Skin	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
HEENT	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Lungs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Heart	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Abdomen	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Lymph Nodes	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Musculoskeletal	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Neurological	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Other: _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

**Vascular Exam**

Pulses:	Left	Right
Carotid	Bounding (3+) <input type="checkbox"/>	Bounding (3+) <input type="checkbox"/>
	Normal (2+) <input type="checkbox"/>	Normal (2+) <input type="checkbox"/>
	Diminished (1+) <input type="checkbox"/>	Diminished (1+) <input type="checkbox"/>
	Absent (0) <input type="checkbox"/>	Absent (0) <input type="checkbox"/>
Femoral	Bounding (3+) <input type="checkbox"/>	Bounding (3+) <input type="checkbox"/>
	Normal (2+) <input type="checkbox"/>	Normal (2+) <input type="checkbox"/>
	Diminished (1+) <input type="checkbox"/>	Diminished (1+) <input type="checkbox"/>
	Absent (0) <input type="checkbox"/>	Absent (0) <input type="checkbox"/>



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

<b>FORM NO. CND005</b>			
Acrostic Identifier:			
Study ID:			
Date source form completed: ____/____/____			
<b>Physical Exam - FollowUp (M3, Interim)</b>			
<b>Vascular Exam</b>			
<b>Pulses:</b>	<b>Left</b>		<b>Right</b>
Popliteal	Bounding (3+) <input type="checkbox"/>	Normal (2+) <input type="checkbox"/>	Bounding (3+) <input type="checkbox"/>
	Diminished (1+) <input type="checkbox"/>	Absent ( 0 ) <input type="checkbox"/>	Normal (2+) <input type="checkbox"/>
			Diminished (1+) <input type="checkbox"/>
			Absent ( 0 ) <input type="checkbox"/>
Posterior Tibial (PT)	Bounding (3+) <input type="checkbox"/>	Normal (2+) <input type="checkbox"/>	Bounding (3+) <input type="checkbox"/>
	Diminished (1+) <input type="checkbox"/>	Absent ( 0 ) <input type="checkbox"/>	Normal (2+) <input type="checkbox"/>
			Diminished (1+) <input type="checkbox"/>
			Absent ( 0 ) <input type="checkbox"/>
Dorsalis Pedis (DP)	Bounding (3+) <input type="checkbox"/>	Normal (2+) <input type="checkbox"/>	Bounding (3+) <input type="checkbox"/>
	Diminished (1+) <input type="checkbox"/>	Absent ( 0 ) <input type="checkbox"/>	Normal (2+) <input type="checkbox"/>
			Diminished (1+) <input type="checkbox"/>
			Absent ( 0 ) <input type="checkbox"/>
<b>PAD Symptoms and Signs:</b>	<b>Left Leg</b>		<b>Right Leg</b>
Skin ulcers?	Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>
Gangrene?	Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>
Ischemic rest pain?	Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>
Pitting Edema (If 3+ is checked, patient is excluded)	3+ <input type="checkbox"/>	2+ <input type="checkbox"/>	3+ <input type="checkbox"/>
	1+ <input type="checkbox"/>	None <input type="checkbox"/>	2+ <input type="checkbox"/>
			1+ <input type="checkbox"/>
			None <input type="checkbox"/>
<b>Questions</b>			
Has the patient experienced any reportable (grade 2 or higher) adverse events since the last visit? (If yes, complete AE form)			Yes <input type="checkbox"/> No <input type="checkbox"/>
Have there been any changes to medications since last visit? (If yes, update medication form)			Yes <input type="checkbox"/> No <input type="checkbox"/>
Has the patient completed Quality of Life Questionnaires (WIQ & PAQ Survey)? (If no, please explain in Comments)			Yes <input type="checkbox"/> No <input type="checkbox"/>
Was the Treadmill Test with pre & post ABIs, COT and PWT completed to send to the Core Lab? (If no, please explain in Comments)			Yes <input type="checkbox"/> No <input type="checkbox"/>
What is your smoking status?		Never <input type="checkbox"/>	Previous <input type="checkbox"/>
			Current <input type="checkbox"/>
			Yr stopped: _____ packs/day: _____
Comments:			

MD Signature \_\_\_\_\_ Date: \_\_\_\_\_  
Entered to eCRF  Initials \_\_\_\_\_



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

FORM NO. CND005

Acrostic Identifier: \_\_\_\_\_

Study ID: \_\_\_\_\_

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

**Physical Exam - Month 6**

Date of Exam: \_\_\_\_/\_\_\_\_/\_\_\_\_       Visit is outside time window      Reason: \_\_\_\_\_

Check this box if re-consent was required

Date patient reconsented: \_\_\_\_/\_\_\_\_/\_\_\_\_      Consent version: \_\_\_\_\_

Vital Signs		Rutherford Category:	Fontaine Classification:
Weight: _____	<input type="checkbox"/> pounds <input type="checkbox"/> kg	0 <input type="checkbox"/>	Stage 1 <input type="checkbox"/> Stage 2a <input type="checkbox"/> Stage 2b <input type="checkbox"/> Stage 3 <input type="checkbox"/> Stage 4 <input type="checkbox"/>
Temperature: _____.____°F	<input type="checkbox"/> oral <input type="checkbox"/> auricle	1 <input type="checkbox"/>	
Respirations: ____ breaths/minute		2 <input type="checkbox"/>	
Heart rate: ____ beats/minute		3 <input type="checkbox"/>	
Blood Pressure: _____ / _____ mmHg (supine)		4 <input type="checkbox"/>	
	SBP      DBP	5 <input type="checkbox"/>	
		6 <input type="checkbox"/>	

**Rutherford Categories:**  
 0=asymptomatic;  
 1=mild claudication;  
 2=moderate claudication;  
 3=severe claudication;  
 4=ischemic rest pain; 5=minor tissue loss;  
 6=Ulceration or gangrene

**Fontaine Classification:** 1=no symptoms; 2a=intermittent claudication w/o pain on resting, but with claudication at a distance of >200 meters; 2b=intermittent claudication w/o pain on resting, but with a claudication distance of <200 meters; 3=nocturnal and/or resting pain; 4=necrosis (death of tissue) and/or gangrene in the limb.

**Exam: If "Abnormal" is checked, please "Describe" the condition and also check if "Clinically Significant"**

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

Organs	Not Examined	Normal	Abnormal	Clinically Significant	Describe
Skin	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
HEENT	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Lungs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Heart	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Abdomen	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Lymph Nodes	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Musculoskeletal	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Neurological	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Other: _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

**Vascular Exam**

Pulses:	Left	Right
Carotid	Bounding (3+) <input type="checkbox"/>	Bounding (3+) <input type="checkbox"/>
	Normal (2+) <input type="checkbox"/>	Normal (2+) <input type="checkbox"/>
	Diminished (1+) <input type="checkbox"/>	Diminished (1+) <input type="checkbox"/>
	Absent (0) <input type="checkbox"/>	Absent (0) <input type="checkbox"/>



# Cardiovascular Cell Therapy Research Network

PACE Protocol Workbook

FORM NO. CND005

Acrostic Identifier: \_\_\_\_\_

Study ID: \_\_\_\_\_

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

## Physical Exam - Month 6

### Vascular Exam

Pulses:	Left	Right
Femoral	Bounding (3+) <input type="checkbox"/> Normal (2+) <input type="checkbox"/> Diminished (1+) <input type="checkbox"/> Absent (0) <input type="checkbox"/>	Bounding (3+) <input type="checkbox"/> Normal (2+) <input type="checkbox"/> Diminished (1+) <input type="checkbox"/> Absent (0) <input type="checkbox"/>
Popliteal	Bounding (3+) <input type="checkbox"/> Normal (2+) <input type="checkbox"/> Diminished (1+) <input type="checkbox"/> Absent (0) <input type="checkbox"/>	Bounding (3+) <input type="checkbox"/> Normal (2+) <input type="checkbox"/> Diminished (1+) <input type="checkbox"/> Absent (0) <input type="checkbox"/>
Posterior Tibial (PT)	Bounding (3+) <input type="checkbox"/> Normal (2+) <input type="checkbox"/> Diminished (1+) <input type="checkbox"/> Absent (0) <input type="checkbox"/>	Bounding (3+) <input type="checkbox"/> Normal (2+) <input type="checkbox"/> Diminished (1+) <input type="checkbox"/> Absent (0) <input type="checkbox"/>
Dorsalis Pedis (DP)	Bounding (3+) <input type="checkbox"/> Normal (2+) <input type="checkbox"/> Diminished (1+) <input type="checkbox"/> Absent (0) <input type="checkbox"/>	Bounding (3+) <input type="checkbox"/> Normal (2+) <input type="checkbox"/> Diminished (1+) <input type="checkbox"/> Absent (0) <input type="checkbox"/>
PAD Symptoms and Signs:	Left Leg	Right Leg
Skin ulcers?	Yes <input type="checkbox"/> No <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>
Gangrene?	Yes <input type="checkbox"/> No <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>
Ischemic rest pain?	Yes <input type="checkbox"/> No <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>
Pitting Edema	3+ <input type="checkbox"/> 2+ <input type="checkbox"/> 1+ <input type="checkbox"/> None <input type="checkbox"/>	3+ <input type="checkbox"/> 2+ <input type="checkbox"/> 1+ <input type="checkbox"/> None <input type="checkbox"/>

### Questions

Has the patient experienced any reportable (grade 2 or higher) adverse events since the last visit? (If yes, complete AE form) Yes  No

Have there been any changes to medications since last visit? (If yes, update medication form) Yes  No

Has the patient completed Quality of Life Questionnaires (WIQ, PAQ, and Patient Expectation Survey)? (If no, please explain in Comments) Yes  No

Was the Treadmill Test with pre & post ABIs, COT and PWT completed to send to the Core Lab? (If no, please explain in Comments) Yes  No

Was the MRI completed to send to the Core Lab? (If no, please explain in Comments) Yes  No

What is your smoking status? Never  Previous  Current   
Yr stopped: \_\_\_\_\_ packs/day: \_\_\_\_\_

Were one 3 ml, one 4 ml and one 10 ml purple top tubes of peripheral blood drawn to ship to the biorepository for FACS analysis and a second 3 ml purple top tube of peripheral blood drawn for plasma and buffy coat collection? (If no, please explain in the Comments) Yes  No

**Verify patient consented to Biorepository before you draw Biorepository bloods.**

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

MD Signature \_\_\_\_\_ Date: \_\_\_\_\_

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



# Cardiovascular Cell Therapy Research Network

## PACE Protocol Workbook

FORM NO. CND007				
Acrostic Identifier:				
Study ID:				
Date source form completed (mm/dd/yyyy): ____/____/____				
<b>Laboratory Tests - Baseline, Week 1, Month 1, Month 6, Interim</b>				
<b>Date specimen obtained:</b>		<b>Date:</b> ____/____/____		<b>Visit Type:</b>
<b>CBC with Differential</b>	<b>Result</b>	<b>Unit</b>	<b>Normal Range</b>	<b>"&gt;" or "&lt;"</b>
WBC		K/mm <sup>3</sup>	3.5-12.0 K/mm <sup>3</sup>	
RBC		M/mm <sup>3</sup>	3.08-6.6 M/mm <sup>3</sup>	
Hgb		gm/dL	11.6-18 gm/dL	
Hct		%	33-54%	
MCV		fL	78-100 fL	
Platelets		K/mm <sup>3</sup>	140-450 K/mm <sup>3</sup>	
<b>WBC Differential</b>				
Neutrophils		%	35-85%	
Lymphocytes		%	10-65%	
Monocytes		%	0-13%	
Eosinophils		%	0-8%	
Basophils		%	0-3.0%	<
<b>Chemistry Profile</b>				
Na+		mmol/L	135-148 mmol/L	
K+		mmol/L	3.3-5.5 mmol/L	
Chloride		mmol/L	95-110 mmol/L	
CO <sub>2</sub>		mmol/L	19-34 mmol/L	
Glucose		mg/dL	50-200 mg/dL	
Calcium		mg/dL	8.0-10.6 mg/dL	
BUN		mg/dL	5-26 mg/dL	
Creatinine		mg/dL	0.4-1.5 mg/dL	<
Magnesium		mg/dL	1.4-3.0 mg/dL	
<b>Hepatic Panel</b>				
Bilirubin-Total		mg/dL	0.0-1.3 mg/dL	<
Bilirubin-Direct		mg/dL	0.0-0.5 mg/dL	<
Total Protein		g/dL	5.4-9.0 g/dL	
Albumin		g/dL	2.6-5.5 g/dL	
ALT		U/L	0.0-60 U/L	<
AST		U/L	0.0-45 U/L	<
Alkaline Phosphatase		U/L	20-136 U/L	<



# Cardiovascular Cell Therapy Research Network

## PACE Protocol Workbook

FORM NO. CND007				
Acrostic Identifier:				
Study ID:				
Date source form completed (mm/dd/yyyy): ____/____/____				
<b>Laboratory Tests - Baseline, Week 1, Month 1, Month 6, Interim</b>				
Lipid Panel	Result	Unit	Normal Range	">" or "<"
Total Cholesterol		mg/dL	0.0-200 mg/dL	<
HDL		mg/dL	29-96 mg/dL	>
LDL		mg/dL	0.0-130 mg/dL	<
Triglycerides		mg/dL	0.0-210 mg/dL	<
<b>Other Tests</b>				
HbA1C		%	4.0-6.9 %	<
eGFR		ml/min/1.73m <sup>2</sup>	60-180	>
hsCRP		mg/L and mg/dL	0.0-4.9	< and >
INR		no units	0.0-1.26	<
Pregnancy Test (women of childbearing potential) <input type="checkbox"/> Not applicable			Negative (urine) < 5.0 mU/ml (quantitative blood)	
Comments:				
<input type="checkbox"/> Investigator reviewed Lab report		Date Investigator reviewed (mm/dd/yyyy): ____/____/____		

Entered to eCRF

Initials \_\_\_\_\_





# Cardiovascular Cell Therapy Research Network

## PACE Protocol Workbook

FORM NO. CND008

Acrostic Identifier:

Study ID:

Date source form completed (mm/dd/yyyy): \_\_\_\_/\_\_\_\_/\_\_\_\_

### ECG - Baseline, BMA, Wk1, M1, M6

Date of Procedure: \_\_\_\_/\_\_\_\_/\_\_\_\_ Time: \_\_\_\_:\_\_\_\_:\_\_\_\_ Visit Type:

HR: \_\_\_\_ bpm Sinus rhythm: No  Yes

ECG NORMAL  ECG NOT NORMAL

If ECG is "not normal", please indicate if Clinically Significant: No  Yes

(If yes, a comment is required and please complete an AE form)

Comments:

Investigator reviewed ECG report Date Investigator reviewed (mm/dd/yyyy): \_\_\_\_/\_\_\_\_/\_\_\_\_

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



# Cardiovascular Cell Therapy Research Network

## PACE Protocol Workbook

FORM NO. CND009			
Acrostic Identifier:			
Study ID:			
Date source form completed (mm/dd/yyyy): ____/____/____			
<b>Treatment Checklist</b>			
If eligible, Proposed Date for Bone Marrow Aspiration (mm/dd/yyyy): ____/____/____			
The following variables are autopopulated from the previously completed Screen/Demographics, ABI/TBI, Exercise Testing, Baseline Risk, Baseline Physical Exam, Baseline Laboratory Tests, and SDCQ Forms:			
Variable	Value	Criteria	
Patient Age		Must be ≥ 40 years old at consent date	
Index Leg		Must be R or L, and same for both BSL tests	
PWT		Must be < 11 minutes on both BSL tests	
Resting ABI (index leg)*		Must be < 0.90 (in the index leg)	
Resting TBI (index leg)*		Must be < 0.70 (in the index leg)	
Rutherford Category		Must be < 4	
Temperature		Must be < 100.4 °F	
Exercise Program		Must be "No"	
Medical Therapy		Must be "No"	
Pitting Edema		Must be < 3+	
PT/INR		Must be < 2.0 secs or taking anticoagulation therapy	
Platelets		Must be ≥ 100 K and ≤ 500 K	
eGFR		Must be ≥ 30	
HbA1C		Must be ≤ 8.5	
SDCQ		Must be classic claudication or atypical leg pain	
* Only one value required for eligibility: Resting ABI OR Resting TBI.			
If any of the variables above have changed since the Baseline Physical Exam or Baseline Laboratory Tests and a more recent exam or test has been done, please enter the updated value, date, and time of the re-check.			
Variable	Value	Date	Time
Temperature		____/____/____	
Pitting Edema		____/____/____	
PT/INR		____/____/____	
Platelets		____/____/____	
eGFR		____/____/____	
HbA1C		____/____/____	
<b>Please answer the following questions:</b>			
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"/>	
Comments:			



# Cardiovascular Cell Therapy Research Network

## PACE Protocol Workbook

FORM NO. CND009	
Acrostic Identifier:	
Study ID:	
Date source form completed (mm/dd/yyyy): ____/____/____	
<b>Treatment Checklist</b>	
<input type="checkbox"/> PI reviewed Treatment Checklist worksheet	Date PI reviewed (mm/dd/yyyy): ____/____/____

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

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

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



<b>FORM NO.CND010</b>
Acrostic Identifier:
Study ID:
Date source form completed (mm/dd/yyyy): ____/____/____
<b>San Diego Claudication Questionnaire (SDCQ) - Baseline</b>

		<u>Right</u>	<u>Left</u>
1) Do you get pain or discomfort in either leg or either buttock on walking? (If no, stop)	No Yes No Response	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
2) Does this pain ever begin when you are standing still or sitting?	No Yes No Response	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
3) In what part of the leg or buttock do you feel this pain?			
a) Pain includes calf/calves	No Yes No Response	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
b) Pain includes thigh/thighs	No Yes No Response	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
c) Pain includes buttock/buttocks	No Yes No Response	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
4) Do you get this pain when you walk uphill or hurry?	No Yes Never walks uphill/hurries No Response	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
5) Do you get this pain when you walk at an ordinary pace on the level?	No Yes No Response	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
6) Does this pain ever disappear while you are walking?	No Yes No Response	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
7) What do you do if you get this pain when you are walking?	Stop or slow down Continue on No Response	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
8) What happens to this pain if you stand still? (if unchanged, stop)	Lessened or relieved Unchanged No Response	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
9) How soon?	10 minutes or less More than 10 minutes No Response	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>

If patient answers 1) = Yes and 2) = No and 3a) = Yes for answers on the index leg, then the patient is eligible for the study.

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



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

FORM NO. CND011	
Acrostic Identifier:	
Study ID:	
Date source form completed (mm/dd/yyyy): ____ / ____ / ____	
<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 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:	

Entered to eCRF

Initials \_\_\_\_\_



# Cardiovascular Cell Therapy Research Network

## PACE Protocol Workbook

FORM NO. CND012

Acrostic Identifier:

Study ID:

### Adverse Events

Date source form completed (mm/dd/yyyy):

Date of Onset (mm/dd/yyyy):

Resolved Date (mm/dd/yyyy):

Date Site Learned of the Event (mm/dd/yyyy):

*Report all Aes rated as severity grade 2 or higher (per CTCAE version 4.0) unless exempt from AE reporting/recording per protocol. (CTCAE=Common Terminology Criteria for Adverse Events)*

1. Adverse Event:

2. Severity:           Grade 1 - Mild (not entered in database)

Grade 2 - Moderate

Grade 3 - Severe

Grade 4 - Life Threatening or Disabling

Grade 5 - Death

3. Was this event expected?    Yes    No

Please refer to the Investigators Brochure. Medical Monitor will be making final determination of expectedness for the purposes of reporting to the DSMB and FDA.

4. Was the patient hospitalized > 24 hours?    Yes    No

4a. Admission Date (mm/dd/yyyy):

4b. Admission Diagnosis:

4c. Date of Discharge (mm/dd/yyyy):

4d. Discharge Diagnosis:

5. Relationship to study product/procedure:  
(Check only one)

Unrelated

Unlikely

Possibly

Probably

Definitely related

6. Related to study procedure:  
(Check only one)

Bone Marrow Aspiration

MRI

Treadmill Test

Study Product Injection

Not related to study procedure

7. Outcome:

Resolved or stabilized without sequelae

Resolved or stabilized with sequelae

Ongoing

Death: AE present at death, but not cause

Death: death due to AE

8. Was this a Serious Adverse Event (SAE)?

Yes

No



# Cardiovascular Cell Therapy Research Network

## PACE Protocol Workbook

FORM NO. CND012

Acrostic Identifier:

Study ID:

### Adverse Events

#### Complete for Serious Adverse Event Only:

Date AE Progressed to SAE (mm/dd/yyyy):

**Note: If event starts as a SAE, enter "Date of Onset" in these date fields**

Date Site Learned AE Progressed to SAE (mm/dd/yyyy):

9. Indicate the outcome or nature of the event that defines it as a Serious Adverse Event (SAE):  
(Check all that apply)

Resulted in death  
9.a.1 If death, enter the date (mm/dd/yyyy) of death:

9.a.2 Was an autopsy performed?  
 Yes  No  Unknown

Was life-threatening  
 Required hospitalization or prolongation of existing hospitalization  
 Resulted in persistent or significant disability/incapacity  
 Resulted in a congenital anomaly/birth defect  
 Other important medical event

10. Describe the clinical history of the SAE:

11. Describe the associated signs and symptoms of the SAE:

12. Specify what the event is related to if not the study product (e.g. study procedure, other conditions/illness):

13. Describe relevant past medical history:

14. Describe the medical management for the SAE:

15. Record abnormal diagnostic studies relevant to SAE:  
**Note: If not applicable, enter "none"**

16. Is the patient currently taking medication in response to SAE?  Yes  No  
**If Yes, confirm that all medications have been reported on the Concomitant Medication Form.**

Comments for page:



# Cardiovascular Cell Therapy Research Network

PACE Protocol Workbook

FORM NO. CND012

Acrostic Identifier:

Study ID:

## Adverse Events

PI reviewed AE

Date PI reviewed AE (mm/dd/yyyy): \_\_\_\_/\_\_\_\_/\_\_\_\_

PI reviewed SAE

Date PI reviewed SAE (mm/dd/yyyy): \_\_\_\_/\_\_\_\_/\_\_\_\_

**Note: Only required if event is a SAE or if AE progressed to SAE**

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

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

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





<b>FORM NO. CND014</b>	
Acrostic Identifier:	
Study ID:	
Date source form completed (mm/dd/yyyy): ____/____/____	
<b>Study Product Injection</b>	
<b>Vital Signs (Pre-Study Product Injection)</b>	
Date: ____/____/____      Time (hhmm 24-hour clock): ____-____	
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 Injection Period</b>	
Procedure Start Date: ____/____/____      Start Time (hhmm 24-hour clock): ____-____	
Procedure Stop Date: ____/____/____      Stop Time (hhmm 24-hour clock): ____-____	
<b>Mark injections below:</b>	
Injection 1	Volume of Injection 1: __ __ ml <input type="checkbox"/> Not done <input type="checkbox"/> Calf <input type="checkbox"/> Thigh
Injection 2	Volume of Injection 2: __ __ ml <input type="checkbox"/> Not done <input type="checkbox"/> Calf <input type="checkbox"/> Thigh
Injection 3	Volume of Injection 3: __ __ ml <input type="checkbox"/> Not done <input type="checkbox"/> Calf <input type="checkbox"/> Thigh
Injection 4	Volume of Injection 4: __ __ ml <input type="checkbox"/> Not done <input type="checkbox"/> Calf <input type="checkbox"/> Thigh
Injection 5	Volume of Injection 5: __ __ ml <input type="checkbox"/> Not done <input type="checkbox"/> Calf <input type="checkbox"/> Thigh
Injection 6	Volume of Injection 6: __ __ ml <input type="checkbox"/> Not done <input type="checkbox"/> Calf <input type="checkbox"/> Thigh
Injection 7	Volume of Injection 7: __ __ ml <input type="checkbox"/> Not done <input type="checkbox"/> Calf <input type="checkbox"/> Thigh
Injection 8	Volume of Injection 8: __ __ ml <input type="checkbox"/> Not done <input type="checkbox"/> Calf <input type="checkbox"/> Thigh
Injection 9	Volume of Injection 9: __ __ ml <input type="checkbox"/> Not done <input type="checkbox"/> Calf <input type="checkbox"/> Thigh
Injection 10	Volume of Injection 10: __ __ ml <input type="checkbox"/> Not done <input type="checkbox"/> Calf <input type="checkbox"/> Thigh





# Cardiovascular Cell Therapy Research Network

## PACE Protocol Workbook

FORM NO. CND014	
Acrostic Identifier:	
Study ID:	
Date source form completed (mm/dd/yyyy): ____/____/____	
<b>Study Product Injection</b>	
<b>Vital Signs (30 mins Post-Study Product Injection)</b>	
Temperature:	_____°F <input type="checkbox"/> oral <input type="checkbox"/> auricle
Respirations:	__ __ breaths/minute
Heart rate:	__ __ __ beats/minute
Blood Pressure:	__ __ __ / __ __ __ mmHg (supine) SBP                  DBP
<b>Vital Signs (60 mins Post-Study Product Injection)</b>	
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:	

Entered to eCRF

Initials \_\_\_\_\_



# Cardiovascular Cell Therapy Research Network

## PACE Protocol Workbook

FORM NO. CND015	
Is this unanticipated problem specific to an individual subject ?	<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 source form completed (mm/dd/yyyy): ____/____/____	
<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>	
<b>Date of the Event:</b>	
<b>Date the site study team had knowledge of the Event:</b>	
<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):	

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

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

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



# Cardiovascular Cell Therapy Research Network

## PACE Protocol Workbook

FORM NO. CND016

Acrostic Identifier:

Study ID:

Date source form completed (mm/dd/yyyy): \_\_\_\_/\_\_\_\_/\_\_\_\_

### 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 with or 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: \_\_\_\_\_

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

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

CCTRN Medical Officer or Designee Review:

Exemption Granted  Deviation Acknowledged

Reportable per site's IRB policies:  Yes-immediate reporting  Yes-continuing review  No-not reportable

Yes  No if Yes, Date Received: \_\_\_\_\_

IRB documentation received?

If No, explain:

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



# Cardiovascular Cell Therapy Research Network

PACE Protocol Workbook

FORM NO.CND020

Acrostic Identifier:

Study ID:

Date of this report: \_\_\_\_/\_\_\_\_/\_\_\_\_

## Peripheral Artery Questionnaire (PAQ) - Baseline, M1, M3, M6, M12

Visit Type:

The following questions refer to blockages in the arteries of your body, particularly your legs, and how that might affect your life. Please read and complete the following questions. There are no right or wrong answers. Please mark the answer that best applies to you.

1. Blockages in the arteries, often referred to as **peripheral vascular disease**, affect different people in different ways. Some feel cramping or aching while others feel fatigue. Which leg (or buttock) causes you the most severe discomfort, fatigue, pain, aching, or cramps?

the **Right** leg (buttock)

The **Left** leg (buttock)

**Both** are the same

Neither

2. Please review the list below and indicate how much limitation you have due to your **peripheral vascular disease** (discomfort, fatigue, pain, aching, or cramps in your calves (or buttocks)) over the past 4 weeks.

Place and **X** in one box on each line

Activity	Extremely Limited	Quite a bit Limited	Moderately Limited	Slightly Limited	Not at all Limited	Limited for other reasons or did not do the activity	No Response
Walking around your home	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Walking 1-2 blocks on <b>level ground</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Walking 1-2 blocks <b>up a hill</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Walking 3-4 blocks on level ground	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Hurrying or jogging (as if to catch a bus)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Vigorous work or exercise	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



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

<b>FORM NO.CND020</b>
Acrostic Identifier:
Study ID:
Date of this report: ____/____/____
<b>Peripheral Artery Questionnaire (PAQ) - Baseline, M1, M3, M6, M12</b>
<b>Visit Type:</b>

3. Compared with 4 weeks ago, have your symptoms of **peripheral vascular disease** (discomfort, fatigue, pain, aching, or cramps in your calves (or buttocks)) changed?

My symptoms have become...

Much worse	Slightly worse	Not changed	Slightly better	Much better	I have had no symptoms over the past 4 weeks	No Response
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

4. Over the past 4 weeks, how many times did you have **discomfort, fatigue, pain, aching, or cramps in your calves (or buttocks)**?

All of the time	Several times per day	At least once a day	3 or more times per week but not every day	1-2 times per week	Less than once a week	Never over the past 4 weeks	No Response
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

5. Over the past 4 weeks, how much has **discomfort, fatigue, pain, aching, or cramps in your calves (or buttocks)** bothered you?

It has been...

Extremely bothersome	Moderately bothersome	Somewhat bothersome	Slightly bothersome	Not at all bothersome	I've had no leg discomfort	No Response
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

6. Over the past 4 weeks, how often have you been awakened with **pain, aching, or cramps in your legs or feet**?

Every night	3 or more times per week but not every night	1-2 times per week	Less than once a week	Never over the past 4 weeks	No Response
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



<b>FORM NO.CND020</b>
Acrostic Identifier:
Study ID:
Date of this report: ____/____/____
<b>Peripheral Artery Questionnaire (PAQ) - Baseline, M1, M3, M6, M12</b>
Visit Type:

7. How satisfied are you that everything possible is being done to treat your **peripheral vascular disease**?

Not satisfied at all	Mostly dissatisfied	Somewhat satisfied	Mostly satisfied	Completely satisfied	No Response
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

8. How satisfied are you with the explanations your doctor has given you about your **peripheral vascular disease**?

Not satisfied at all	Mostly dissatisfied	Somewhat satisfied	Mostly satisfied	Completely satisfied	No Response
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

9. Overall, how satisfied are you with the current treatment of your **peripheral vascular disease**?

Not satisfied at all	Mostly dissatisfied	Somewhat satisfied	Mostly satisfied	Completely satisfied	No Response
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

10. Over the past 4 weeks, how much has your **peripheral vascular disease** limited your enjoyment of life?

It has extremely limited my enjoyment of life	It has limited my enjoyment of life quite a bit	It has moderately limited my enjoyment of life	It has slightly limited my enjoyment of life	It has not limited my enjoyment of life at all	No Response
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

11. If you had to spend the rest of your life with your **peripheral vascular disease** the way it is right now, how would you feel about this?

Not satisfied at all	Mostly dissatisfied	Somewhat satisfied	Mostly satisfied	Completely satisfied	No Response
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

12. Over the past 4 weeks, how often have you felt discouraged or down in the dumps because of your **peripheral vascular disease**?

I felt that way all of the time	I felt that way most of the time	I occasionally felt that way	I rarely felt that way	I never felt that way	No Response
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



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

<b>FORM NO.CND020</b>
Acrostic Identifier:
Study ID:
Date of this report: ____/____/____
<b>Peripheral Artery Questionnaire (PAQ) - Baseline, M1, M3, M6, M12</b>
<b>Visit Type:</b>

13. How much does your **peripheral vascular disease** affect your lifestyle? Please indicate how your **discomfort, fatigue, pain, aching, or cramps in your calves (or buttocks)** may have limited your participation in the following activities over the past 4 weeks.

Please place an **X** in one box on each line

Activity	Severely limited	Limited quite a bit	Moderately limited	Slightly limited	Did not limit at all	Does not apply or did not do for other reasons	No Response
Hobbies, recreational activities	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Visiting family or friends out of your home	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Working or doing household chores	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Entered to eCRF

Initials \_\_\_\_\_





# Cardiovascular Cell Therapy Research Network

PACE Protocol Workbook

FORM NO.CND021

Acrostic Identifier:

Study IC

Date source form completed (mm/dd/yyyy): \_\_\_\_/\_\_\_\_/\_\_\_\_

## Patient Expectation Survey - Baseline

1) When were you diagnosed with PAD?

- 0-12 months
- 1-2 years
- 3-5 years
- Greater than 5 years
- No Response

2) I expect my leg pain to be reduced after study treatment.

- |                          |                          |                            |                          |                          |                          |
|--------------------------|--------------------------|----------------------------|--------------------------|--------------------------|--------------------------|
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Strongly Agree           | Agree                    | Neither agree nor disagree | Disagree                 | Strongly disagree        | No Response              |

3) I expect to feel better overall after study treatment.

- |                          |                          |                            |                          |                          |                          |
|--------------------------|--------------------------|----------------------------|--------------------------|--------------------------|--------------------------|
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Strongly Agree           | Agree                    | Neither agree nor disagree | Disagree                 | Strongly disagree        | No Response              |

4) I expect to be able to walk without pain after receiving study treatment.

- |                          |                          |                            |                          |                          |                          |
|--------------------------|--------------------------|----------------------------|--------------------------|--------------------------|--------------------------|
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Strongly Agree           | Agree                    | Neither agree nor disagree | Disagree                 | Strongly disagree        | No Response              |

5) I am confident that treatment with stem cells will decrease my leg pain.

- |                          |                          |                            |                          |                          |                          |
|--------------------------|--------------------------|----------------------------|--------------------------|--------------------------|--------------------------|
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Strongly Agree           | Agree                    | Neither agree nor disagree | Disagree                 | Strongly disagree        | No Response              |

6) I expect to have some minor inconveniences related to my participation in this study.

- |                          |                          |                            |                          |                          |                          |
|--------------------------|--------------------------|----------------------------|--------------------------|--------------------------|--------------------------|
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Strongly Agree           | Agree                    | Neither agree nor disagree | Disagree                 | Strongly disagree        | No Response              |

7) I think stem cells are effective for treating disease.

- |                          |                          |                            |                          |                          |                          |
|--------------------------|--------------------------|----------------------------|--------------------------|--------------------------|--------------------------|
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Strongly Agree           | Agree                    | Neither agree nor disagree | Disagree                 | Strongly disagree        | No Response              |

8) I expect to be tired due to logistical complications of participating in the study (i.e. driving to clinic, wait time to see doctor, etc).

- |                          |                          |                            |                          |                          |                          |
|--------------------------|--------------------------|----------------------------|--------------------------|--------------------------|--------------------------|
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Strongly Agree           | Agree                    | Neither agree nor disagree | Disagree                 | Strongly disagree        | No Response              |



FORM NO.CND021
Acrostic Identifier:
Study IC
Date source form completed (mm/dd/yyyy): ____/____/____
<b>Patient Expectation Survey - Baseline</b>

9) I think it will be easy to participate in this study.

- Strongly Agree    
  Agree    
  Neither agree nor disagree    
  Disagree    
  Strongly disagree    
  No Response

10) In general, I expect stem cells to make me feel better.

- Strongly Agree    
  Agree    
  Neither agree nor disagree    
  Disagree    
  Strongly disagree    
  No Response

11) What is your hope for this treatment with regard to your leg pain?

- Small reduction in pain
- Moderate reduction in pain
- Large reduction in pain
- Elimination of pain
- No Response

12) Do you know anyone personally who has received stem cells to treat a disease?

- Yes      No      No Response

If Yes, please list relationship below and comment on if this influenced your decision to participate in the study?

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13) How long did it take you to decide to participate in this research study using stem cells for your Peripheral Artery Disease (PAD)?

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14) Did you discuss the study with anyone before deciding to participate?

- Yes      No      No Response

If Yes, please list their relationship with you below:

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15) What motivated you to participate in this PAD study?

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# Cardiovascular Cell Therapy Research Network

PACE Protocol Workbook

FORM NO.CND021

Acrostic Identifier:

Study IC

Date source form completed (mm/dd/yyyy): \_\_\_\_/\_\_\_\_/\_\_\_\_

## Patient Expectation Survey - *Baseline*

16) Do you have a person(s) who will help you during your participation in this study? (For example, drive or accompany you to study visits, remind you to take your temperature, etc.)

Yes  No  No Response

If Yes, please list this person(s) relationship to you:

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



FORM NO.CND023

Acrostic Identifier:

Study ID:

Date source form completed (mm/dd/yyyy): \_\_\_\_/\_\_\_\_/\_\_\_\_

**Patient Expectation Survey - Month 6**

Please indicate which treatment the PI thinks this patient received.

- Stem Cells
- Placebo
- Don't know

1) Please indicate which treatment you think you received.

- Stem Cells
- Placebo
- Don't know

2) My leg pain was reduced after study treatment.

- |                          |                          |                            |                          |                          |                          |
|--------------------------|--------------------------|----------------------------|--------------------------|--------------------------|--------------------------|
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Strongly Agree           | Agree                    | Neither agree nor disagree | Disagree                 | Strongly disagree        | No Response              |

3) I felt better overall after study treatment.

- |                          |                          |                            |                          |                          |                          |
|--------------------------|--------------------------|----------------------------|--------------------------|--------------------------|--------------------------|
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Strongly Agree           | Agree                    | Neither agree nor disagree | Disagree                 | Strongly disagree        | No Response              |

4) I walk without pain after receiving study treatment.

- |                          |                          |                            |                          |                          |                          |
|--------------------------|--------------------------|----------------------------|--------------------------|--------------------------|--------------------------|
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Strongly Agree           | Agree                    | Neither agree nor disagree | Disagree                 | Strongly disagree        | No Response              |

5) My leg pain decreased after being treated with stem cells.

- |                          |                          |                            |                          |                          |                          |
|--------------------------|--------------------------|----------------------------|--------------------------|--------------------------|--------------------------|
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Strongly Agree           | Agree                    | Neither agree nor disagree | Disagree                 | Strongly disagree        | No Response              |

6) I had some minor inconveniences related to my participation in this study.

- |                          |                          |                            |                          |                          |                          |
|--------------------------|--------------------------|----------------------------|--------------------------|--------------------------|--------------------------|
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Strongly Agree           | Agree                    | Neither agree nor disagree | Disagree                 | Strongly disagree        | No Response              |

7) I think stem cells are effective for treating disease.

- |                          |                          |                            |                          |                          |                          |
|--------------------------|--------------------------|----------------------------|--------------------------|--------------------------|--------------------------|
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Strongly Agree           | Agree                    | Neither agree nor disagree | Disagree                 | Strongly disagree        | No Response              |



FORM NO.CND023

Acrostic Identifier:

Study ID:

Date source form completed (mm/dd/yyyy): \_\_\_\_/\_\_\_\_/\_\_\_\_

**Patient Expectation Survey - Month 6**

8) I was tired due to logistical complications of participating in the study (i.e. driving to clinic, wait time to see doctor, etc).

- |                          |                          |                            |                          |                          |                          |
|--------------------------|--------------------------|----------------------------|--------------------------|--------------------------|--------------------------|
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Strongly Agree           | Agree                    | Neither agree nor disagree | Disagree                 | Strongly disagree        | No Response              |

9) It was easy to participate in this study.

- |                          |                          |                            |                          |                          |                          |
|--------------------------|--------------------------|----------------------------|--------------------------|--------------------------|--------------------------|
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Strongly Agree           | Agree                    | Neither agree nor disagree | Disagree                 | Strongly disagree        | No Response              |

10) In general, stem cells made me feel better.

- |                          |                          |                            |                          |                          |                          |
|--------------------------|--------------------------|----------------------------|--------------------------|--------------------------|--------------------------|
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Strongly Agree           | Agree                    | Neither agree nor disagree | Disagree                 | Strongly disagree        | No Response              |

11) During this study, did your leg pain:

- Increase
- Decrease
- Stay the same
- Not sure
- No Response

12) What was the hardest part of being in this study?

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13) Based on your experience from this study, would you participate in another stem cell study?

- Yes  No  No Response

Please explain your answer.

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14) What about the study treatment did you like?

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

FORM NO.CND023

Acrostic Identifier:

Study ID:

Date source form completed (mm/dd/yyyy): \_\_\_\_/\_\_\_\_/\_\_\_\_

**Patient Expectation Survey - Month 6**

15) What about the study treatment did you NOT like?

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16) If you had to do this again, would you prefer biological treatment (stem cell or gene therapy) or conventional therapy (revascularization or pills) for your leg pain? Please explain:

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Entered to eCRF

Initials \_\_\_\_\_



# Cardiovascular Cell Therapy Research Network

## PACE Protocol Workbook

FORM NO.CND022

Acrostic Identifier:

Study ID:

Date of this report: \_\_\_\_/\_\_\_\_/\_\_\_\_

### Walking Impairment Questionnaire (WIQ) - Baseline, M1, M3, M6

Visit Type:

**1. WALKING IMPAIRMENT:** These questions ask about the reasons why you have difficulty walking. We would like to know how much difficulty you have walking because of each of these problems during the past month. By difficulty, we mean how hard it was or how much physical effort it takes to walk because of each of these problems.

A. PAD Specific Questions	Leg	Degree of Difficulty					NR
		None	Slight	Some	Much	Very	
1. Pain, aching, or cramps in your calves? (or buttocks)	Right <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Left <input type="checkbox"/>						
	Both <input type="checkbox"/>						
	NR <input type="checkbox"/>						

B. Differential Diagnosis	Degree of Difficulty					
	None	Slight	Some	Much	Very	NR
1. Pain, stiffness, or aching in your joints (ankles, knees, or hips)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Weakness in one or both of your legs?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Pain or discomfort in your chest?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Shortness of breath?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Heart palpitations?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Other problems? (Please list) _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**2. WALKING DISTANCE:** Report the degree of physical difficulty that best describes how hard it is for you to walk on level ground without stopping to rest for each of the following distances:

A. Distance	Degree of Difficulty					NR
	None	Slight	Some	Much	Unable	
1. Walking indoors such as around your home?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Walking 50 feet?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Walking 150 feet? (1/2 block)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Walking 300 feet? (1 block)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Walking 900 feet? (3 blocks)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Walking 1500 feet? (5 blocks)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



# Cardiovascular Cell Therapy Research Network

## PACE Protocol Workbook

FORM NO.CND022

Acrostic Identifier:

Study ID:

Date of this report: \_\_\_\_/\_\_\_\_/\_\_\_\_

### Walking Impairment Questionnaire (WIQ) - *Baseline, M1, M3, M6*

Visit Type:

**3. WALKING SPEED:** These questions refer to how fast you are able to walk one city block on level ground during the last month. Tell us the degree of physical difficulty required for you to walk at each of these speeds without stopping to rest.

A. Speed	Degree of Difficulty					NR
	None	Slight	Some	Much	Unable	
1. Walking 1 block slowly?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Walking 1 block at an average speed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Walking 1 block quickly?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Running or jogging one block?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**4. STAIR CLIMBING:** These questions refer to how many flights of stairs you are able to climb. Tell us the degree of physical difficulty required for you to climb stairs for each of these questions without stopping to rest.

Stairs	Degree of Difficulty					NR
	None	Slight	Some	Much	Unable	
1. Climbing 1 flight of stairs?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Climbing 2 flight of stairs?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Climbing 3 flight of stairs?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Entered to eCRF

Initials \_\_\_\_\_





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

<b>FORM NO. CND024</b>			
Acrostic Identifier:			
Study ID:			
Date source form completed (mm/dd/yyyy): ____/____/____			
<b>Medication Allergies</b>			
The Drug Allergies section must be completed by answering allergy questions and clicking on Add Allergies or Update Allergies. Entering this information triggers payment for this form.			
Drug Allergies:	NKDA <input type="checkbox"/>	Yes <input type="checkbox"/>	Please list:

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



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

**FORM NO. CND025**

Acrostic Identifier:	
Study ID:	

**Medications**

Enter or update medication information here. If patient is taking no medication, no entry is required. To add a medication, enter medication information and click Add Medication or Update Medication. Repeat for each medication. Medications will be listed in a table below as they are entered. To modify medication information, click 'Select' to the right of the medication in the table, edit the information and click Update Medication.

#	Date Source Form Completed	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"/>			
19							<input type="checkbox"/>			
20							<input type="checkbox"/>			

Comments

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



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

FORM NO. CND026
Acrostic Identifier:
Study ID:
Date source form completed (mm/dd/yyyy): ____/____/____
<b>Randomization Form</b>
Confirmed Date for Bone Marrow Aspiration (mm/dd/yyyy): ____/____/____
Comments:

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



<b>FORM NO. CND027</b>	
Acrostic Identifier:	
Study ID:	
Date source form completed: ____/____/____	
<b>Follow-Up Telephone Contact</b>	
Date of Call/Contact: ____/____/____	
Contact Initiated by (check one):	<input type="checkbox"/> Site <input type="checkbox"/> Subject
Questions being answered by:	<input type="checkbox"/> Patient <input type="checkbox"/> Family Member <input type="checkbox"/> Other
<b>Section 1 - Vital Status</b>	
a. What is the patient's vital status?	<input type="checkbox"/> Living <input type="checkbox"/> Deceased
If deceased, what is the known cause of death?	
<b>Section 2 - Hospitalizations and Diagnoses</b>	
Since the last time we spoke, have you had any of the following limb-related procedures?	
b. Limb amputation	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
If yes, provide estimated date:	
c. Toe amputation	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
If yes, provide estimated date:	
d. Ulcer or gangrene on treated leg	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
If yes, provide estimated date:	
e. Other vascular procedures (caths, stents, balloons, etc.)	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
1) Describe:	Date:
2) Describe:	Date:
3) Describe:	Date:
Since the last time we spoke, have you had any hospitalizations for the following heart-related procedures?	
f. Heart attack (myocardial infarction)	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
If yes, provide estimated date:	
g. Bypass surgery (CABG)	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
If yes, provide estimated date:	
h. Stroke	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
If yes, provide estimated date:	



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

FORM NO. CND027	
Acrostic Identifier:	
Study ID:	
Date source form completed: ____/____/____	
<b>Follow-Up Telephone Contact</b>	
i. Other heart procedures (caths, stents, balloons, etc.) <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	
1) Describe:	Date:
2) Describe:	Date:
3) Describe:	Date:
j. Any cancer diagnoses (including skin) <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	
If yes, provide estimated date:	
Indicate type of cancer(s):	
k. Was the PAQ completed? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	
Comments:	
Name of person collecting information:	



# Cardiovascular Cell Therapy Research Network

PACE Protocol Workbook

FORM NO. CND028	
Acrostic Identifier:	
Study ID:	
Date source form completed (mm/dd/yyyy): ____/____/____	
<b>End of Study</b>	
Date of final follow-up study visit: ____/____/____	
<b>Reason for discharge from the study:</b>	
<input type="checkbox"/> Completed study	
<input type="checkbox"/> Withdrawn	Date of discharge from study (mm/dd/yyyy)
<input type="checkbox"/> Lost to follow-up	Date: ____/____/____
<input type="checkbox"/> Screen Failure	
<b>If "Withdrawn", please check the primary reason for withdrawal:</b>	
<i>Reasons that require follow-up:</i>	
<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:
<i>Reasons that DO NOT require follow-up:</i>	
<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:
<b>Please verify the following tasks are complete:</b>	
<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.
<b>Comments:</b>	

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

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

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

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

Entered to eCRF

Initials \_\_\_\_\_

FORM NO. CND029	
Acrostic Identifier:	
Study ID:	
Date source form completed (mm/dd/yyyy): ____/____/____	
<b>Exercise Treadmill Test - Baseline 1, Baseline 2, M3, M6</b>	
<b>Visit Type:</b>	
<b>Treadmill Start Date:</b> ____/____/____ <b>Start Time (hhmm 24-hour clock):</b> ____	
Was the test conducted according to the Modified Gardner Protocol?    Yes <input type="checkbox"/> No <input type="checkbox"/>	
Date/Time of <u>last</u> claudication symptoms prior to treadmill test: Date: ____/____/____      Time (hhmm 24-hour clock): ____	
Did the subject reach claudication during the test?    Yes <input type="checkbox"/> No <input type="checkbox"/> If "Yes", Claudication Onset Time (COT):    __ __ minutes    __ __ seconds	
Peak Walking Time (PWT):    __ __ minutes    __ __ seconds Treadmill Elevation (% Grade) @ PWT:    __ __ %	
<b>ECG:</b>	ST Segment Changes:    Yes <input type="checkbox"/> No <input type="checkbox"/> <i>(If Yes to either, then please fill out an AE form)</i> Arrhythmias:    Yes <input type="checkbox"/> No <input type="checkbox"/>
Primary reason for stopping treadmill test: <input type="checkbox"/> CLAUDICATION <input type="checkbox"/> OTHER If "Other", please specify: _____	
Describe claudication symptoms: (check all that apply and/or enter "Other" description) <input type="checkbox"/> Fatigue <input type="checkbox"/> Cramping <input type="checkbox"/> Pain <input type="checkbox"/> Other: _____	Describe any other symptoms noted by the subject during the treadmill test: (check all that apply and/or enter "Other" description) <input type="checkbox"/> Chest pain <input type="checkbox"/> Shortness of breath <input type="checkbox"/> Dizziness <input type="checkbox"/> Joint Pain <input type="checkbox"/> Other: _____
Index Leg: <input type="checkbox"/> R <input type="checkbox"/> L <input type="checkbox"/> Both    (If "Both" checked, patient does not qualify for study)	
Comments:	

Person(s) responsible for conducting the treadmill test:

\_\_\_\_\_

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



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

FORM NO. CND030			
Acrostic Identifier:			
Study ID:			
Date source form completed (mm/dd/yyyy): ____/____/____			
<b>ABI / TBI - Baseline, Month 3, Month 6</b>			
Date of Assessment (mm/dd/yyyy): ____/____/____			Visit Type:
Measurement Collected:	<input type="checkbox"/> ABI	<input type="checkbox"/> TBI	<i>Baseline selected based on calculated Resting ABI Measurements (see below); M3 &amp; M6 - same as Baseline.</i>

<b>Pre-Exercise ABI Pressure Readings</b>				Check this box if non-compressible vessels <input type="checkbox"/>			
Time (hhmm 24-hour clock): ____				<i>Shaded fields are filled in by ABI eCRF programming</i>			
<i>all pressures are Doppler SBP (mmHg)</i>	1st Reading	2nd Reading	Unable to Obtain	Average Reading	<i>These fields are determined based on "Readings"</i>		
Right Arm Pressure	_____	_____	<input type="checkbox"/>	_____	Highest Average Arm:		Highest Average Arm Reading
Left Arm Pressure	_____	_____	<input type="checkbox"/>	_____	Right <input type="checkbox"/>	Left <input type="checkbox"/>	_____
Right DP Ankle Pressure	_____	_____	<input type="checkbox"/>	_____	Right Highest Average ankle:		Highest Average R-ankle Reading
Right PT Ankle Pressure	_____	_____	<input type="checkbox"/>	_____	DP <input type="checkbox"/>	PT <input type="checkbox"/>	_____
Left DP Ankle Pressure	_____	_____	<input type="checkbox"/>	_____	Left Highest Average ankle:		Highest Average L-ankle Reading
Left PT Ankle Pressure	_____	_____	<input type="checkbox"/>	_____	DP <input type="checkbox"/>	PT <input type="checkbox"/>	_____
<b>Pre-Exercise ABI Measurements (Calculated by Database)</b>							
Resting Right Leg ABI	_____			If the <b>index leg</b> Resting Leg ABI (R or L) is <0.9, select ABI. If the <b>index leg</b> Resting Leg ABI (R or L) is >1.3, or documented as unable to obtain due to non-compressible vessels, select TBI. If the <b>index leg</b> Resting Leg ABI (R or L) is ≥0.9 and ≤1.3, with no documentation of non-compressible vessels, screen failure.			
Resting Left Leg ABI	_____						
Reminder: Please be sure to click "Save Incomplete" for Core Lab review before Adding/Updating eCRF.							

<b>Pre-Exercise TBI Pressure Readings</b>				<i>If ABI selected, this section will be blank.</i>			
Time (hhmm 24-hour clock): ____				<i>Shaded fields are filled in by TBI eCRF programming</i>			
<i>all pressures are PPG</i>	1st Reading	2nd Reading	Unable to Obtain	Average Reading	<i>These fields are determined based on "Readings"</i>		
Right Arm Pressure	_____	_____	<input type="checkbox"/>	_____	Highest Average Arm:		Highest Average Arm Reading
Left Arm Pressure	_____	_____	<input type="checkbox"/>	_____	Right <input type="checkbox"/>	Left <input type="checkbox"/>	_____
Right Toe Pressure	_____	_____	<input type="checkbox"/>	_____	Highest Average Toe:		Highest Average Toe Reading
Left Toe Pressure	_____	_____	<input type="checkbox"/>	_____	Right <input type="checkbox"/>	Left <input type="checkbox"/>	_____
<b>Pre-Exercise TBI Measurements (Calculated by Database)</b>							
Resting Right TBI	_____						
Resting Left TBI	_____						
Reminder: Please be sure to click "Save Incomplete" for Core Lab review before Adding/Updating eCRF.							





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

FORM NO. CND030	
Acrostic Identifier:	
Study ID:	
Date source form completed (mm/dd/yyyy): ____/____/____	
<b>ABI / TBI - Baseline, Month 3, Month 6</b>	

<b>Post-Exercise Pressure Readings (ABI only)</b>		
<i>After the treadmill test, take ONE systolic pressure reading at the identified vessels <u>within 2 minutes of exercise cessation</u> and enter the pressures obtained in the appropriate Measurement box. Only the <u>index leg</u> Post-Exercise Measurements needed at M3 and M6.</i>		Post-Exercise Measurements (Pressure Readings)
Highest Average ARM from RESTING ABI:	Right <input type="checkbox"/> Left <input type="checkbox"/>	_____
Highest Average Right-ANKLE from RESTING ABI:	DP <input type="checkbox"/> PT <input type="checkbox"/>	_____
Highest Average Left-ANKLE from RESTING ABI:	DP <input type="checkbox"/> PT <input type="checkbox"/>	_____
Were arm and ankle pressures obtained within 2 minutes of the treadmill testing? <input type="checkbox"/> Yes <input type="checkbox"/> No		
If No, how many minutes after the treadmill test were the pressures obtained? _____ minutes		
If there was no pressure sound detected at first attempt in any given vessel, did the pressures return eventually for all vessels for which this question applies? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Pressure was detected at first attempt		
If Yes, how many minutes after the treadmill test did the pressures return? _____ minutes		
<b>Post-Exercise ABI Measurements (Calculated by Database)</b>		
Post-Exercise Right Leg ABI	_____	Right Leg Percent Decrease in ABI _____ %
Post-Exercise Left Leg ABI	_____	Left Leg Percent Decrease in ABI _____ %
Comments:		

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



## **CCTRN Case Report Form Workbooks**

- CND001** Screening
- CND002** Demographics
- CND003** Eligibility
- CND004** Baseline Risk
- CND005** Physical Exams
- CND007** Labs
- CND008** ECG
- CND009** Treatment Checklist
- CND010** San Diego Claudication Questionnaire (SDCQ)
- CND011** Bone Marrow Aspiration
- CND012** Adverse Event/Serious Adverse Event
- CND014** Study Product Injection
- CND015** Unanticipated Problem
- CND016** Protocol Deviation
- CND020** Peripheral Arterial Questionnaire (PAQ)
- CND021** Patient Expectation Survey - Baseline
- CND023** Patient Expectation Survey - 6M
- CND022** Walking Impairment Questionnaire (WIQ)
- CND024** Allergies
- CND025** Medications
- CND026** Randomization
- CND028** End of Study
- CND029** Treadmill Test
- CND030** ABI/TBI