FORM NO. CND001

Study ID:

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

PACE Screening Form

Date screened (mm/dd/yyyy): ____/____/____

Sex: M ☐ F ☐

Age: _____ (years)

Hispanic, Latino or Spanish Origin: Y ☐ N ☐

Race (choose one):

- White ☐
- Black or African American ☐
- Asian ☐
- Native Hawaiian or Other Pacific Islander ☐
- American Indian or Alaska Native ☐
- Other ☐

How did the patient first find out about this study? Please choose the closest answer.

- ☐ Cardiologist or other physician
- ☐ Research nurse or other non-physician medical personnel
- ☐ Clinicaltrials.gov website
- ☐ Internet (not including clinicaltrials.gov)
- ☐ Facebook or Twitter
- ☐ Newspaper/Magazine
- ☐ Hospital flyer or other print advertisement
- ☐ Radio/TV
- ☐ Referred by a friend or other non-medical person
- ☐ Other (please specify):_____
- ☐ No Response

Inclusion Criteria

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)?			☐ 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) ?			☐ Y	☐ N	
3) Is the patient ≥ 40 years old?			☐ 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: _____	☐ Y	☐ N	☐ 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?			☐ Y	☐ N	☐ Not Available

FORM NO. CND001

Study ID:

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

PACE Screening Form

	Y	N	Not Available
6) Does the patient agree to participate in this trial?	☐	☐	☐

If no, please check a reason below (required):

- ☐ Declined
- ☐ Does not want placebo
- ☐ Could not decide
- ☐ Too far / Transportation issues
- ☐ Family issues or concerns
- ☐ Unwilling to participate in study procedures and/or follow-up
- ☐ Too busy / Too much going on
- ☐ Other (please specify) _____

Exclusion Criteria ☐ **No evidence in medical record of an exclusion**

If box above is checked, the rest can be blank, or select 1 or more criteria below for a screen failure.

	Y	N	Not Available
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)?	☐	☐	☐
8) Is the patient unable to complete the treadmill testing per protocol requirements?	☐	☐	☐
9) Is the patient able to walk for more than 12 minutes on the treadmill during treadmill testing?	☐	☐	☐
10) Does the patient identify both legs as equivocally symptomatic or alternate between symptomatic legs on the baseline treadmill tests?	☐	☐	☐
11) Does the patient have critical limb ischemia (Rutherford classes 4 or 5)?	☐	☐	☐
12) Has the patient had a recent (< 3 months) infrainguinal revascularization (surgery or endovascular revascularization) or is planned during the study period?	☐	☐	☐
13) Does the patient have peripheral pitting edema >2+?	☐	☐	☐
14) Is the patient pregnant, planning to become pregnant in the next 12 months, or lactating?	☐	☐	☐
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)?	☐	☐	☐
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)?	☐	☐	☐

FORM NO. CND001			
Study ID:			
Date source form completed (mm/dd/yyyy): ____/____/____			
PACE Screening Form			
17) Does the patient have known HIV positive or have active HBV or HCV disease?	☐ Y	☐ N	☐ Not Available
18) Does the patient have a history of cancer within the last 5 years, except basal cell skin carcinoma?	☐ Y	☐ N	☐ Not Available
19) Does the patient have any bleeding diathesis defined as INR ≥ 2.0 (off anticoagulation therapy) or history of platelet count less than 100,000 or hemophilia?	☐ Y	☐ N	☐ 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?	☐ Y	☐ N	☐ Not Available
21) Does the patient have chronic kidney disease (eGFR <30 by MDRD or Mayo or Cockcroft-Gault formula)?	☐ Y	☐ N	☐ Not Available
22) Does the patient have uncontrolled diabetes (HbA1C > 8.5)?	☐ Y	☐ N	☐ Not Available
23) Is the patient planning a change (initiation or termination) to active involvement in a supervised exercise program during study participation?	☐ Y	☐ N	☐ Not Available
24) Is the patient planning to change PAD medical therapy during the duration of the study?	☐ Y	☐ N	☐ Not Available
25) Is the patient unable to provide written informed consent due to cognitive or language barriers?	☐ Y	☐ N	☐ Not Available
26) Is the patient enrolled in another clinical investigative trial?	☐ Y	☐ N	☐ Not Available
27) Does the patient have any condition requiring immunosuppressant medications?	☐ Y	☐ N	☐ Not Available
28) Does the patient have a history of inflammatory or progressively fibrotic conditions?	☐ Y	☐ N	☐ 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.	☐ Y	☐ N	☐ Not Available
30) Does the patient have myelodysplastic syndrome (MDS)?	☐ Y	☐ N	☐ Not Available

FORM NO. CND001			
Study ID:			
Date source form completed (mm/dd/yyyy): ____/____/____			
PACE Screening Form			
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?	☐ Y	☐ N	☐ 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?	☐ Y	☐ N	☐ Not Available
Comments			

Entered to eCRF ☐ Initials _____

FORM NO. CND002

Study ID:

Acrostic Identifier (if applicable):

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

Demographics

Last Name:

First Name:

Middle Initial:

Has the participant signed the consent form? Y ☐ N ☐

If yes, Date of Consent: (mm/dd/yyyy)

____/____/_____

Biorepository Consents signed:

Samples for future research	Y ☐	N ☐
Samples for genetic research	Y ☐	N ☐
Inclusion of de-dentified information	Y ☐	N ☐

If no, please check a reason below:

- ☐ Declined
- ☐ Does not want placebo
- ☐ Could not decide
- ☐ Too far / Transportation issues
- ☐ Family issues or concerns
- ☐ Unwilling to participate in study procedures and/or follow-up
- ☐ Too busy / Too much going on
- ☐ Other (please specify): _____

Agreed to be contacted for future trial opportunities: Y ☐ N ☐ N/A (IRB does not allow) ☐

Date of Birth: (mm/dd/yyyy) ____/____/_____

Gender M ☐ F ☐

Hispanic, Latino, or Spanish Origin Y ☐ N ☐ No response ☐

Race (choose one):

- White ☐
- Black or African American ☐
- Asian ☐
- Native Hawaiian or Other Pacific Islander ☐
- American Indian or Alaska Native ☐
- Other ☐
- No response ☐

Marital Status (choose one):

- Married ☐
- Living with a partner ☐
- Single/never married ☐
- Widowed ☐
- Divorced ☐
- Separated ☐
- No response ☐

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

Entered to eCRF ☐ Initials _____

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)**
☐	☐	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.
☐	☐	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.
☐	☐	Patient is at least 40 years of age.
☐	☐	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.
☐	☐	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)**
☐	☐	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).
☐	☐	Inability to complete treadmill testing per protocol requirements.
☐	☐	Ability to walk for more than 12 minutes on the treadmill during treadmill testing.
☐	☐	Identified both legs as equivocally symptomatic or alternated between sympotomatic legs on the baseline treadmill tests.
☐	☐	Critical limb ischemia (Rutherford classes 4 or 5).
☐	☐	Recent (< 3 months) infrainguinal revascularization (surgery or endovascular revascularization) or planned during study period.
☐	☐	Peripheral pitting edema >2+.
☐	☐	Pregnant, planning to become pregnant in the next 12 months, or lactating status.
☐	☐	CHF hospitalization within the last 1 month prior to enrollment (as defined by the standard definitions of CHF and ACS by the AHA).
☐	☐	Acute coronary syndrome in the last 1 month prior to enrollment (as defined by the standard definitions of CHF and ACS by the AHA).
☐	☐	HIV positive or active HBV or HCV disease.
☐	☐	History of cancer within the last 5 years, except basal cell skin carcinoma.
☐	☐	Any bleeding diathesis defined as an INR ≥2.0 (off anticoagulation therapy) or history of platelet count less than 100,000 or hemophilia.
☐	☐	Contraindication to MRI (including knee/tibial/fibular replacement hardware in the index leg) or known allergy to MR contrast media.
☐	☐	Chronic kidney disease (eGFR < 30 by MDRD or Mayo or Cockcroft-Gault formula).
☐	☐	Uncontrolled diabetes (HbA1C >8.5).

FORM NO. CND003	
Acrostic Identifier:	
Study ID:	
Date source form completed (mm/dd/yyyy): _____/_____/_____	

Eligibility Criteria		
Y	**N**	**Exclusion Criteria (Must answer No to all questions to be eligible)**
☐	☐	Planned change (iniate or terminate) to active involvement in a supervised exercise program during study participation.
☐	☐	Plans to change PAD medical therapy during the duration of the study.
☐	☐	Unable to provide written informed consent due to cognitive or language barriers.
☐	☐	Enrolled in another clinical investigative trial.
☐	☐	Any condition requiring immunosuppressant medications.
☐	☐	History of inflammatory or progressively fibrotic conditions.
☐	☐	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.
☐	☐	Myelodysplastic syndrome (MDS).
☐	☐	Any untreated stenosis > 70% of the distal aorta, common iliac, or external iliac arteries by CT, Angiography or MRI imaging.
☐	☐	Any other clinical condition that in the opinion of the PI makes the patient not suitable to participate in this trial.

☐	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:

☐ PI reviewed Eligibility Criteria worksheet Date PI reviewed (mm/dd/yyyy): ____/____/_____

PI Signature _____ Date: _____

RNC Signature _____ Date: _____

Entered to eCRF ☐ Initials _____

FORM NO. CND004						
Acrostic Identifier:						
Study ID:						
Date source form completed (mm/dd/yyyy): _____/_____/_____						
Baseline Risk Factors						
Diabetes	No ☐		Type I ☐		Type II ☐	
Diabetes Treatment:	Oral Hypoglycemics ☐		Neither ☐			
	Insulin ☐		Both ☐			
Hypertension	No ☐		Yes ☐			
Hypertension Treatment:	No medication ☐					
	1 medication ☐					
	2 or more medications ☐					
Hyperlipidemia	No ☐		Yes ☐			
Hyperlipidemia Treatment:	Diet controlled ☐					
	Drug controlled ☐					
	Neither ☐					
Smoking	Never ☐		Previous ☐		Current ☐	
			Yr stopped: _____		packs/day: __	
Comorbidities						
History of cancer	No ☐		Yes ☐		Unknown ☐	
(If <5 years, patient is excluded unless basal cell carcinoma)			If yes, type of cancer:_____			
			Date of diagnosis: ___/___/___			
History of renal insufficiency	No ☐		Yes ☐		Unknown ☐	
If yes, is the patient on dialysis?	No ☐		Yes ☐		Unknown ☐	
Angina	No ☐		Stable ☐		Unstable ☐	
Carotid disease, asymptomatic	No ☐		Yes ☐			
History of TIAs	No ☐		Yes ☐			
History of stroke	No ☐		Current Deficit ☐		Completely Resolved ☐	
History of aneurysm	No ☐		Yes ☐			
Obese	No ☐		Yes ☐			

PAD History						
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	☐	Yes	☐	☐	___/___/_____
Lower extremity revascularization -- open surgical (endarterectomy)	No	☐	Yes	☐	☐	___/___/_____
Lower extremity revascularization -- endovascular	No	☐	Yes	☐	☐	___/___/_____
History of claudication	No	☐	Yes	☐	☐	

FORM NO. CND004	
Acrostic Identifier:	
Study ID:	
Date source form completed (mm/dd/yyyy): _____/_____/_____	

Baseline Risk Factors

Describe Other Revascularization Procedures:

1.
2.
3.
4.
5.

Other Cardiac History

Prior to this visit, have you undergone treatment for:

Congestive heart failure	No	☐	Yes	☐
PCI	No	☐	Yes	☐
Previous MI	No	☐	Yes	☐
Bypass surgery	No	☐	Yes	☐
Cardiac catheterization	No	☐	Yes	☐
Carotid endarterectomy/angioplasty	No	☐	Yes	☐
Cardiac pacemaker	No	☐	Yes	☐
Valvular heart disease	No	☐	Yes	☐
If yes, check all that apply:			mitral	☐
			aortic	☐
			pulmonic	☐
			tricuspid	☐
Other cardiovascular interventions	No	☐	Yes	☐

If yes, please describe other coronary interventions:

Procedure:

1.
2.
3.
4.
5.

Questions:

If female, are you of child bearing potential? No ☐ Yes ☐ N/A ☐

If no, check one: post menopausal ☐ surgically sterile ☐

Comments:

Entered to eCRF ☐ Initials _____

FORM NO. CND005	
Acrostic Identifier:	
Study ID:	
Date source form completed (mm/dd/yyyy): _____/_____/_____	

Physical Exam - *Baseline*

Date of Exam: _____/_____/_____

☐ **Check this box if re-consent was required**

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

Vital Signs	
Height:	_____ ☐ inches ☐ cm
Weight:	_____ ☐ pounds ☐ kg
Temperature:	__ __.__°F ☐ oral ☐ auricle
Respirations:	__ __ breaths/minute
Heart rate:	__ __ __ beats/minute
Blood Pressure:	___ ___ ___ / ___ ___ ___ mmHg (supine) SBP DBP

Rutherford Category:

0 ☐	Eligible
1 ☐	Eligible
2 ☐	Eligible
3 ☐	Eligible
4 ☐	Ineligible
5 ☐	Ineligible
6 ☐	Ineligible

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:

Stage 1	☐
Stage 2a	☐
Stage 2b	☐
Stage 3	☐
Stage 4	☐

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.

PAD Treatment:

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, **patient is excluded**)	Yes ☐ No ☐
Have you changed medical therapy for PAD within the last four weeks? (If yes, please describe changes in comments -- **patient is excluded**)	Yes ☐ No ☐

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

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

FORM NO. CND005	
Acrostic Identifier:	
Study ID:	
Date source form completed (mm/dd/yyyy): _____/_____/_____	

Physical Exam - *Baseline*

Vascular Exam

Pulses:	Left	Right
Carotid	Bounding (3+) ☐ Normal (2+) ☐ Diminished (1+) ☐ Absent (0) ☐	Bounding (3+) ☐ Normal (2+) ☐ Diminished (1+) ☐ Absent (0) ☐
Femoral	Bounding (3+) ☐ Normal (2+) ☐ Diminished (1+) ☐ Absent (0) ☐	Bounding (3+) ☐ Normal (2+) ☐ Diminished (1+) ☐ Absent (0) ☐
Popliteal	Bounding (3+) ☐ Normal (2+) ☐ Diminished (1+) ☐ Absent (0) ☐	Bounding (3+) ☐ Normal (2+) ☐ Diminished (1+) ☐ Absent (0) ☐
Posterior Tibial (PT)	Bounding (3+) ☐ Normal (2+) ☐ Diminished (1+) ☐ Absent (0) ☐	Bounding (3+) ☐ Normal (2+) ☐ Diminished (1+) ☐ Absent (0) ☐
Dorsalis Pedis (DP)	Bounding (3+) ☐ Normal (2+) ☐ Diminished (1+) ☐ Absent (0) ☐	Bounding (3+) ☐ Normal (2+) ☐ Diminished (1+) ☐ Absent (0) ☐
PAD Symptoms and Signs:	Left Leg	Right Leg
Skin ulcers?	Yes ☐ No ☐	Yes ☐ No ☐
Gangrene?	Yes ☐ No ☐	Yes ☐ No ☐
Ischemic rest pain?	Yes ☐ No ☐	Yes ☐ No ☐
Pitting Edema (If 3+ is checked, patient is excluded)	3+ ☐ 2+ ☐ 1+ ☐ None ☐	3+ ☐ 2+ ☐ 1+ ☐ None ☐

Questions

Has the patient experienced any reportable (grade 2 or higher) adverse events since consent signed? (If yes, complete AE form)	Yes ☐ No ☐
Has the patient completed the San Diego Claudication Questionnaire? (If no, please explain in Comments)	Yes ☐ No ☐
Has the patient completed Quality of Life Questionnaires (WIQ, PAQ, and Patient Expectaion Survey)? (If no, please explain in Comments)	Yes ☐ No ☐
Was the Infectious Disease lab panel drawn and sent for analysis? (If no, please enter a reason 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 ☐
Comments:	

MD Signature_____ Date:_____

Entered to eCRF ☐ Initials _____

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** **Date patient reconsented:** _____/_____/_____ **Consent version:**	**Visit Type:**

Vital Signs

Weight:	_____ ☐ pounds ☐ kg
Temperature:	__ __.__°F ☐ oral ☐ 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	☐	☐	☐	☐	
HEENT	☐	☐	☐	☐	
Lungs	☐	☐	☐	☐	
Heart	☐	☐	☐	☐	
Abdomen	☐	☐	☐	☐	
Lymph Nodes	☐	☐	☐	☐	
Musculoskeletal	☐	☐	☐	☐	
Neurological	☐	☐	☐	☐	
Other: _____	☐	☐	☐	☐	

Vascular Exam

Pulses:	Left	Right
Carotid	Bounding (3+) ☐ Normal (2+) ☐ Diminished (1+) ☐ Absent (0) ☐	Bounding (3+) ☐ Normal (2+) ☐ Diminished (1+) ☐ Absent (0) ☐
Femoral	Bounding (3+) ☐ Normal (2+) ☐ Diminished (1+) ☐ Absent (0) ☐	Bounding (3+) ☐ Normal (2+) ☐ Diminished (1+) ☐ Absent (0) ☐

FORM NO. CND005	
Acrostic Identifier:	
Study ID:	

Date source form completed: _____/_____/_____

Physical Exam - FollowUp (BMA)

Vascular Exam

Pulses:	Left	Right
Popliteal	Bounding (3+) ☐ Normal (2+) ☐ Diminished (1+) ☐ Absent (0) ☐	Bounding (3+) ☐ Normal (2+) ☐ Diminished (1+) ☐ Absent (0) ☐
Posterior Tibial (PT)	Bounding (3+) ☐ Normal (2+) ☐ Diminished (1+) ☐ Absent (0) ☐	Bounding (3+) ☐ Normal (2+) ☐ Diminished (1+) ☐ Absent (0) ☐
Dorsalis Pedis (DP)	Bounding (3+) ☐ Normal (2+) ☐ Diminished (1+) ☐ Absent (0) ☐	Bounding (3+) ☐ Normal (2+) ☐ Diminished (1+) ☐ Absent (0) ☐
PAD Symptoms and Signs:	Left Leg	Right Leg
Skin ulcers?	Yes ☐ No ☐	Yes ☐ No ☐
Gangrene?	Yes ☐ No ☐	Yes ☐ No ☐
Ischemic rest pain?	Yes ☐ No ☐	Yes ☐ No ☐
Pitting Edema (If 3+ is checked, patient is excluded)	3+ ☐ 2+ ☐ 1+ ☐ None ☐	3+ ☐ 2+ ☐ 1+ ☐ None ☐

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 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 ☐
What is your smoking status?	Never ☐ Previous ☐ Yr stopped: _____ Current ☐ 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) **Verify patient consented to Biorepository before you draw Biorepository bloods.**	Yes ☐ No ☐
Comments:	

MD Signature_____ Date:_____

Entered to eCRF ☐ Initials _____

FORM NO. CND005	
Acrostic Identifier:	
Study ID:	
Date source form completed (mm/dd/yyyy): _____/_____/_____	

Physical Exam - FollowUp (SPI, Wk1)

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		**Infection Assessment**	**BMA**		**SPI**
			Left Iliac Crest Site	*Right Iliac Crest Site*	*Injection Sites*
Weight:	_____ ☐ pounds ☐ kg	Erythema	Y☐ N☐	Y☐ N☐	Y☐ N☐
Temperature:	__ __.__°F ☐ oral ☐ auricle	Hematoma	Y☐ N☐	Y☐ N☐	Y☐ N☐
Respirations:	__ __ breaths/minute	Pain	Y☐ N☐	Y☐ N☐	Y☐ N☐
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				

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	☐	☐	☐	☐	
HEENT	☐	☐	☐	☐	
Lungs	☐	☐	☐	☐	
Heart	☐	☐	☐	☐	
Abdomen	☐	☐	☐	☐	
Lymph Nodes	☐	☐	☐	☐	
Musculoskeletal	☐	☐	☐	☐	
Neurological	☐	☐	☐	☐	
Other: _____	☐	☐	☐	☐	

Vascular Exam

Pulses:	Left	Right
Carotid	Bounding (3+) ☐ Normal (2+) ☐ Diminished (1+) ☐ Absent (0) ☐	Bounding (3+) ☐ Normal (2+) ☐ Diminished (1+) ☐ Absent (0) ☐

FORM NO. CND005	
Acrostic Identifier:	
Study ID:	
Date source form completed (mm/dd/yyyy): _____/_____/_____	

Physical Exam - FollowUp (SPI, Wk1)

Vascular Exam

Pulses:	Left	Right
Femoral	Bounding (3+) ☐ Normal (2+) ☐ Diminished (1+) ☐ Absent (0) ☐	Bounding (3+) ☐ Normal (2+) ☐ Diminished (1+) ☐ Absent (0) ☐
Popliteal	Bounding (3+) ☐ Normal (2+) ☐ Diminished (1+) ☐ Absent (0) ☐	Bounding (3+) ☐ Normal (2+) ☐ Diminished (1+) ☐ Absent (0) ☐
Posterior Tibial (PT)	Bounding (3+) ☐ Normal (2+) ☐ Diminished (1+) ☐ Absent (0) ☐	Bounding (3+) ☐ Normal (2+) ☐ Diminished (1+) ☐ Absent (0) ☐
Dorsalis Pedis (DP)	Bounding (3+) ☐ Normal (2+) ☐ Diminished (1+) ☐ Absent (0) ☐	Bounding (3+) ☐ Normal (2+) ☐ Diminished (1+) ☐ Absent (0) ☐
PAD Symptoms and Signs:	Left Leg	Right Leg
Skin ulcers?	Yes ☐ No ☐	Yes ☐ No ☐
Gangrene?	Yes ☐ No ☐	Yes ☐ No ☐
Ischemic rest pain?	Yes ☐ No ☐	Yes ☐ No ☐
Pitting Edema (If 3+ is checked, patient is excluded)	3+ ☐ 2+ ☐ 1+ ☐ None ☐	3+ ☐ 2+ ☐ 1+ ☐ None ☐

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 ☐
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) **Verify patient consented to Biorepository before you draw Biorepository bloods.**	Yes ☐ No ☐
Comments:	

MD Signature_____ Date:_____

Entered to eCRF ☐ Initials _____

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** **Date patient reconsented:** _____/_____/_____ **Consent version:**	**Visit Type:**

Vital Signs

Weight:	_____ ☐ pounds ☐ kg
Temperature:	__ __.__°F ☐ oral ☐ 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	☐	☐	☐	☐	
HEENT	☐	☐	☐	☐	
Lungs	☐	☐	☐	☐	
Heart	☐	☐	☐	☐	
Abdomen	☐	☐	☐	☐	
Lymph Nodes	☐	☐	☐	☐	
Musculoskeletal	☐	☐	☐	☐	
Neurological	☐	☐	☐	☐	
Other: _____	☐	☐	☐	☐	

Vascular Exam

Pulses:	Left	Right
Carotid	Bounding (3+) ☐ Normal (2+) ☐ Diminished (1+) ☐ Absent (0) ☐	Bounding (3+) ☐ Normal (2+) ☐ Diminished (1+) ☐ Absent (0) ☐
Femoral	Bounding (3+) ☐ Normal (2+) ☐ Diminished (1+) ☐ Absent (0) ☐	Bounding (3+) ☐ Normal (2+) ☐ Diminished (1+) ☐ Absent (0) ☐

FORM NO. CND005	
Acrostic Identifier:	
Study ID:	

Date source form completed: _____/_____/_____

Physical Exam - FollowUp (M1)

Vascular Exam

Pulses:	Left	Right
Popliteal	Bounding (3+) ☐ Normal (2+) ☐ Diminished (1+) ☐ Absent (0) ☐	Bounding (3+) ☐ Normal (2+) ☐ Diminished (1+) ☐ Absent (0) ☐
Posterior Tibial (PT)	Bounding (3+) ☐ Normal (2+) ☐ Diminished (1+) ☐ Absent (0) ☐	Bounding (3+) ☐ Normal (2+) ☐ Diminished (1+) ☐ Absent (0) ☐
Dorsalis Pedis (DP)	Bounding (3+) ☐ Normal (2+) ☐ Diminished (1+) ☐ Absent (0) ☐	Bounding (3+) ☐ Normal (2+) ☐ Diminished (1+) ☐ Absent (0) ☐
PAD Symptoms and Signs:	Left Leg	Right Leg
Skin ulcers?	Yes ☐ No ☐	Yes ☐ No ☐
Gangrene?	Yes ☐ No ☐	Yes ☐ No ☐
Ischemic rest pain?	Yes ☐ No ☐	Yes ☐ No ☐
Pitting Edema (If 3+ is checked, patient is excluded)	3+ ☐ 2+ ☐ 1+ ☐ None ☐	3+ ☐ 2+ ☐ 1+ ☐ None ☐

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 Survey)? (If no, please explain in Comments)	Yes ☐ No ☐
What is your smoking status?	Never ☐ Previous ☐ Yr stopped: _____ Current ☐ 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) **Verify patient consented to Biorepository before you draw Biorepository bloods.**	Yes ☐ No ☐
Comments:	

MD Signature_____ Date:_____

Entered to eCRF ☐ Initials _____

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** **Date patient reconsented:** _____/_____/_____ **Consent version:**	**Visit Type:**

Vital Signs

Weight:	_____ ☐ pounds ☐ kg
Temperature:	__ __.__°F ☐ oral ☐ 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	☐	☐	☐	☐	
HEENT	☐	☐	☐	☐	
Lungs	☐	☐	☐	☐	
Heart	☐	☐	☐	☐	
Abdomen	☐	☐	☐	☐	
Lymph Nodes	☐	☐	☐	☐	
Musculoskeletal	☐	☐	☐	☐	
Neurological	☐	☐	☐	☐	
Other: _____	☐	☐	☐	☐	

Vascular Exam

Pulses:	Left	Right
Carotid	Bounding (3+) ☐ Normal (2+) ☐ Diminished (1+) ☐ Absent (0) ☐	Bounding (3+) ☐ Normal (2+) ☐ Diminished (1+) ☐ Absent (0) ☐
Femoral	Bounding (3+) ☐ Normal (2+) ☐ Diminished (1+) ☐ Absent (0) ☐	Bounding (3+) ☐ Normal (2+) ☐ Diminished (1+) ☐ Absent (0) ☐

FORM NO. CND005	
Acrostic Identifier:	
Study ID:	

Date source form completed: _____/_____/_____

Physical Exam - FollowUp (M3, Interim)

Vascular Exam

Pulses:	Left	Right
Popliteal	Bounding (3+) ☐ Normal (2+) ☐ Diminished (1+) ☐ Absent (0) ☐	Bounding (3+) ☐ Normal (2+) ☐ Diminished (1+) ☐ Absent (0) ☐
Posterior Tibial (PT)	Bounding (3+) ☐ Normal (2+) ☐ Diminished (1+) ☐ Absent (0) ☐	Bounding (3+) ☐ Normal (2+) ☐ Diminished (1+) ☐ Absent (0) ☐
Dorsalis Pedis (DP)	Bounding (3+) ☐ Normal (2+) ☐ Diminished (1+) ☐ Absent (0) ☐	Bounding (3+) ☐ Normal (2+) ☐ Diminished (1+) ☐ Absent (0) ☐
PAD Symptoms and Signs:	Left Leg	Right Leg
Skin ulcers?	Yes ☐ No ☐	Yes ☐ No ☐
Gangrene?	Yes ☐ No ☐	Yes ☐ No ☐
Ischemic rest pain?	Yes ☐ No ☐	Yes ☐ No ☐
Pitting Edema (If 3+ is checked, patient is excluded)	3+ ☐ 2+ ☐ 1+ ☐ None ☐	3+ ☐ 2+ ☐ 1+ ☐ None ☐

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 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 ☐
What is your smoking status?	Never ☐ Previous ☐ Yr stopped: _____ Current ☐ packs/day: ___
Comments:	

MD Signature_____ Date:_____

Entered to eCRF ☐ Initials _____

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	
Weight:	_____ ☐ pounds ☐ kg
Temperature:	__ __.__ °F ☐ oral ☐ auricle
Respirations:	__ __ breaths/minute
Heart rate:	__ __ __ beats/minute
Blood Pressure:	__ __ __ / __ __ __ mmHg (supine) SBP DBP

Rutherford Category:

0 ☐
1 ☐
2 ☐
3 ☐
4 ☐
5 ☐
6 ☐

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:

Stage 1 ☐
Stage 2a ☐
Stage 2b ☐
Stage 3 ☐
Stage 4 ☐

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	☐	☐	☐	☐	
HEENT	☐	☐	☐	☐	
Lungs	☐	☐	☐	☐	
Heart	☐	☐	☐	☐	
Abdomen	☐	☐	☐	☐	
Lymph Nodes	☐	☐	☐	☐	
Musculoskeletal	☐	☐	☐	☐	
Neurological	☐	☐	☐	☐	
Other: _____	☐	☐	☐	☐	

Vascular Exam

Pulses:	Left	Right
Carotid	Bounding (3+) ☐ Normal (2+) ☐ Diminished (1+) ☐ Absent (0) ☐	Bounding (3+) ☐ Normal (2+) ☐ Diminished (1+) ☐ Absent (0) ☐

FORM NO. CND005	
Acrostic Identifier:	
Study ID:	
Date source form completed: _____/_____/_____	

Physical Exam - Month 6

Vascular Exam

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

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 ☐ Yr stopped: _____ Current ☐ 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) **Verify patient consented to Biorepository before you draw Biorepository bloods.**	Yes ☐ No ☐
Comments:	

MD Signature_____ Date:_____

Entered to eCRF ☐ Initials _____

FORM NO. CND007				
Acrostic Identifier:				
Study ID:				
Date source form completed (mm/dd/yyyy): _____/_____/_____				
Laboratory Tests - Baseline, Week 1, Month 1, Month 6, Interim				
Date specimen obtained: **Date:** _____/_____/_____ **Visit Type:**				
CBC with Differential	**Result**	**Unit**	**Normal Range**	**">" or "<"**
WBC		K/mm^3	3.5-12.0 K/mm^3	
RBC		M/mm^3	3.08-6.6 M/mm^3	
Hgb		gm/dL	11.6-18 gm/dL	
Hct		%	33-54%	
MCV		fL	78-100 fL	
Platelets		K/mm^3	140-450 K/mm^3	
WBC Differential				
Neutrophilis		%	35-85%	
Lymphocytes		%	10-65%	
Monocytes		%	0-13%	
Eosinophils		%	0-8%	
Basophils		%	0-3.0%	<
Chemisty Profile				
Na+		mmol/L	135-148 mmol/L	
K+		mmol/L	3.3-5.5 mmol/L	
Chloride		mmol/L	95-110 mmol/L	
CO_2		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	
Hepatic Panel				
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	<

FORM NO. CND007				
Acrostic Identifier:				
Study ID:				
Date source form completed (mm/dd/yyyy): _____/_____/_____				
Laboratory Tests - Baseline, Week 1, Month 1, Month 6, Interim				
Lipid Panel	**Result**	**Unit**	**Normal Range**	**">" or "<"**
Total Cholestrol		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	<
Other Tests				
HbA1C		%	4.0-6.9 %	<
eGFR		ml/min/1.73m^2	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) ☐ Not applicable			Negative (urine) < 5.0 mU/ml (quantitative blood)	
Comments:				
☐ Investigator reviewed Lab report		Date Investigator reviewed (mm/dd/yyyy): ___/___/___		

Entered to eCRF ☐ Initials _____

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 _____

FORM NO. CND009

Acrostic Identifier:

Study ID:

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

Treatment Checklist

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 ºF
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		____/____/_____	

Please answer the following questions:

1. Since the baseline exam and tests, has there been a change in the patient's condition that would prohibit continuation in the study? (If yes, please explain in Comments)	Yes ☐	No ☐
2. Is there any other reason you think this patient should not continue in the study? (If yes, please explain in the Comments)	Yes ☐	No ☐

Comments:

FORM NO. CND009
Acrostic Identifier:
Study ID:
Date source form completed (mm/dd/yyyy): _____/_____/_____
Treatment Checklist
☐ PI reviewed Treatment Checklist worksheet Date PI reviewed (mm/dd/yyyy):____/____/_____

PI Signature_____ Date:_____

RNC Signature_____ Date:_____

Entered to eCRF ☐ Initials _____

FORM NO.CND010
Acrostic Identifier:
Study ID:
Date source form completed (mm/dd/yyyy): _____/_____/_____

San Diego Claudication Questionnaire (SDCQ) - *Baseline*

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

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 _____

FORM NO. CND011	
Acrostic Identifier:	
Study ID:	
Date source form completed (mm/dd/yyyy): _____/_____/_____	
Bone Marrow Aspiration	
Procedure Date:	_____/_____/_____
Procedure Venue:	☐ Patient Room ☐ Cath Lab ☐ OR
Time initial aspiration start:	__ __:__ __
Time aspiration complete:	__ __:__ __
Total amount aspirated:	__ __ __ ml
Did the patient experience an adverse event during the procedure? (If yes, complete AE form)	Yes ☐ No ☐
Were concomitant medications given? (If yes, add to medication form)	Yes ☐ No ☐
Comments:	

Entered to eCRF ☐ Initials _____

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

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 mediciation in response to SAE? ☐ Yes ☐ No
If Yes, confirm that all medications have been reported on the Concomitant Medication Form.

Comments for page:

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 _____

FORM NO. CND014	
Acrostic Identifier:	
Study ID:	
Date source form completed (mm/dd/yyyy): _____/_____/_____	
Study Product Injection	
Vital Signs (Pre-Study Product Injection)	
Date: _____/_____/_____ Time (hhmm 24-hour clock): __ __ __ __	
Temperature:	_____°F ☐ oral ☐ auricle
Respirations:	__ __ breaths/minute
Heart rate:	__ __ __ beats/minute
Blood Pressure:	__ __ __ / __ __ __ mmHg (supine) SBP DBP
Study Product Injection Period	
Procedure Start Date: ___/___/_____	Start Time (hhmm 24-hour clock): __ __ __ __
Procedure Stop Date: ___/___/_____	Stop Time (hhmm 24-hour clock): __ __ __ __

		Mark injections below:
Injection 1	Volume of Injection 1: __ __ ml ☐ Not done ☐ Calf ☐ Thigh	
Injection 2	Volume of Injection 2: __ __ ml ☐ Not done ☐ Calf ☐ Thigh	
Injection 3	Volume of Injection 3: __ __ ml ☐ Not done ☐ Calf ☐ Thigh	
Injection 4	Volume of Injection 4: __ __ ml ☐ Not done ☐ Calf ☐ Thigh	
Injection 5	Volume of Injection 5: __ __ ml ☐ Not done ☐ Calf ☐ Thigh	
Injection 6	Volume of Injection 6: __ __ ml ☐ Not done ☐ Calf ☐ Thigh	
Injection 7	Volume of Injection 7: __ __ ml ☐ Not done ☐ Calf ☐ Thigh	
Injection 8	Volume of Injection 8: __ __ ml ☐ Not done ☐ Calf ☐ Thigh	
Injection 9	Volume of Injection 9: __ __ ml ☐ Not done ☐ Calf ☐ Thigh	
Injection 10	Volume of Injection 10: __ __ ml ☐ Not done ☐ Calf ☐ Thigh	

FORM NO. CND014	
Acrostic Identifier:	
Study ID:	
Date source form completed (mm/dd/yyyy): _____/_____/_____	
Study Product Injection	
Vital Signs (30 mins Post-Study Product Injection)	
Temperature:	_____°F ☐ oral ☐ auricle
Respirations:	__ __ breaths/minute
Heart rate:	__ __ __ beats/minute
Blood Pressure:	__ __ __ / __ __ __ mmHg (supine) SBP DBP
Vital Signs (60 mins Post-Study Product Injection)	
Temperature:	_____°F ☐ oral ☐ auricle
Respirations:	__ __ breaths/minute
Heart rate:	__ __ __ beats/minute
Blood Pressure:	__ __ __ / __ __ __ mmHg (supine) SBP DBP
Questions	
1. Was the procedure prematurely stopped? (If yes, complete AE or SAE, and/or UP form)	Yes ☐ No ☐
2. Was the procedure restarted?	Yes ☐ No ☐ N/A ☐
3. Did the patient experience an adverse event during the procedure? (If yes, complete AE or SAE form)	Yes ☐ No ☐
4. Were concomitant medications given? (If yes, add to Medication form)	Yes ☐ No ☐
Comments:	

Entered to eCRF ☐ Initials _____

FORM NO. CND015

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

Unanticipated Problem (UP) Report

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

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

Date of the Event:

Date the site study team had knowledge of the Event:

This Event meets the criteria for an unanticipated problem because:

☐	1	**Unanticipated:** The event is unexpected in terms of nature, severity or frequency given the research procedures described in the protocol, consent, etc. or given the characteristics of the population being studied.
☐	2	**Related:** The event is related or possibly related to participation in the research. There is a reasonable possibility that the incident, experience, event, or outcome may have been caused by the procedures involved in research.
☐	3	**Serious:** The event placed subjects or others at greater risk (including physical, psychological, economic, or social harm) that was previously known or recognized or resulted in harm to the subject or others.

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

Describe the type of event:

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

Description of the unanticipated problem:

Provide a plan to prevent the problem from reoccurring in the future (indicate if protocol or consent modifications are required due to the event):

PI Signature_____ Date:_____

RNC Signature_____ Date:_____

Entered to eCRF ☐ Initials _____

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:

☐	1	The event resulted in an accidental or unintentional change to the IRB approved protocol and procedures with or without prior sponsor approval.
☐	2	The event affected the participant's rights, safety, or welfare, or the integrity of the resultant data.

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

Describe 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
IRB documentation received?	☐ Yes ☐ No if Yes, Date Received: _____ If No, explain:

DCC Signature_____ Date:_____

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	☐	☐	☐	☐	☐	☐	☐
Walking 1-2 blocks on **level ground**	☐	☐	☐	☐	☐	☐	☐
Walking 1-2 blocks **up a hill**	☐	☐	☐	☐	☐	☐	☐
Walking 3-4 blocks on level ground	☐	☐	☐	☐	☐	☐	☐
Hurrying or jogging (as if to catch a bus)	☐	☐	☐	☐	☐	☐	☐
Vigorous work or exercise	☐	☐	☐	☐	☐	☐	☐

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

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
☐	☐	☐	☐	☐	☐	☐

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
☐	☐	☐	☐	☐	☐	☐	☐

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
☐	☐	☐	☐	☐	☐	☐

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
☐	☐	☐	☐	☐	☐

FORM NO.CND020
Acrostic Identifier:
Study ID:
Date of this report: _____/_____/_____
Peripheral Artery Questionnaire (PAQ) - *Baseline, M1, M3, M6, M12*
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
☐	☐	☐	☐	☐	☐

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
☐	☐	☐	☐	☐	☐

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
☐	☐	☐	☐	☐	☐

10. Over the <u>past 4 weeks,</u> 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
☐	☐	☐	☐	☐	☐

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

Not satisfied at all	Mostly dissatisfied	Somewhat satisfied	Mostly satisfied	Completely satisfied	No Response
☐	☐	☐	☐	☐	☐

12. Over the <u>past 4 weeks,</u> 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
☐	☐	☐	☐	☐	☐

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

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	☐	☐	☐	☐	☐	☐	☐
Visiting family or friends out of your home	☐	☐	☐	☐	☐	☐	☐
Working or doing household chores	☐	☐	☐	☐	☐	☐	☐

Entered to eCRF ☐ Initials _____

FORM NO.CND021
Acrostic Identifier:
Study ID
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.

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

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

☐ 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.

☐ 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.

☐ 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.

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

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

☐ 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).

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

FORM NO.CND021
Acrostic Identifier:
Study ID
Date source form completed (mm/dd/yyyy): _____/_____/_____
Patient Expectation Survey - *Baseline*

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?

_____
_____
_____

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

_____
_____
_____

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:

_____
_____
_____

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

_____
_____
_____

FORM NO.CND021
Acrostic Identifier:
Study ID
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:

_____

_____

_____

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.

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

3) I felt better overall after study treatment.

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

4) I walk without pain after receiving study treatment.

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

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

☐ 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.

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

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

☐ 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).

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

9) It was easy to participate in this study.

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

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

☐ 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?

_____
_____
_____

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

Yes ☐ No ☐ No Response ☐

Please explain your answer.

_____
_____
_____

14) What about the study treatment did you like?

_____
_____
_____

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?

_____
_____
_____

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:

_____
_____
_____
_____
_____

Entered to eCRF ☐ Initials _____

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					
		None	Slight	Some	Much	Very	NR
1. Pain, aching, or cramps in your calves? (or buttocks)	Right ☐ Left ☐ Both ☐ NR ☐	☐	☐	☐	☐	☐	☐

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

2. <u>WALKING DISTANCE</u>: 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 <u>each</u> of the following distances:

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

NR = No Response

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**					
	None	**Slight**	**Some**	**Much**	**Unable**	**NR**
1. Walking 1 block slowly?	☐	☐	☐	☐	☐	☐
2. Walking 1 block at an average speed?	☐	☐	☐	☐	☐	☐
3. Walking 1 block quickly?	☐	☐	☐	☐	☐	☐
4. Running or jogging one block?	☐	☐	☐	☐	☐	☐

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**					
	None	**Slight**	**Some**	**Much**	**Unable**	**NR**
1. Climbing 1 flight of stairs?	☐	☐	☐	☐	☐	☐
2. Climbing 2 flight of stairs?	☐	☐	☐	☐	☐	☐
3. Climbing 3 flight of stairs?	☐	☐	☐	☐	☐	☐

Entered to eCRF ☐ Initials _____

NR = No Response

FORM NO. CND024			
Acrostic Identifier:			
Study ID:			
Date source form completed (mm/dd/yyyy): ____/____/_____			
Medication Allergies			
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 ☐	Yes ☐	Please list:

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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							☐			
2							☐			
3							☐			
4							☐			
5							☐			
6							☐			
7							☐			
8							☐			
9							☐			
10							☐			
11							☐			
12							☐			
13							☐			
14							☐			
15							☐			
16							☐			
17							☐			
18							☐			
19							☐			
20							☐			

Comments

Entered to eCRF ☐ Initials _____

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

Entered to eCRF ☐ Initials _____

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

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

FORM NO. CND028	
Acrostic Identifier:	
Study ID:	

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

End of Study

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

Reason for discharge from the study:

- ☐ Completed study
- ☐ Withdrawn — Date of discharge from study (mm/dd/yyy)
- ☐ Lost to follow-up — Date: _____/_____/_____
- ☐ Screen Failure

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

Reasons that require follow-up:

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

Reasons that DO NOT require follow-up:

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

Please verify the following tasks are complete:

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

Comments:

PI Signature _____ Date: _____

RNC Signature _____ Date: _____

Entered to eCRF ☐ Initials _____

FORM NO. CND029	
Acrostic Identifier:	
Study ID:	

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

Exercise Treadmill Test - *Baseline 1, Baseline 2, M3, M6*

Visit Type:

Treadmill Start Date: _____/_____/_____ **Start Time (hhmm 24-hour clock):** __ __ __ __

Was the test conducted according to the Modified Gardner Protocol? Yes ☐ No ☐

Date/Time of last claudication symptoms prior to treadmill test:

Date: _____/_____/_____ Time (hhmm 24-hour clock): __ __ __ __

Did the subject reach claudication during the test? Yes ☐ No ☐

If "Yes", Claudication Onset Time (COT): __ __ minutes __ __ seconds

Peak Walking Time (PWT): __ __ minutes __ __ seconds

Treadmill Elevation (% Grade) @ PWT: __ __ %

ECG: ST Segment Changes: Yes ☐ No ☐

Arrythmias: Yes ☐ No ☐

(If Yes to either, then please fill out an AE form)

Primary reason for stopping treadmill test: ☐ CLAUDICATION ☐ OTHER

If "Other", please specify: _____

Describe claudication symptoms: (check all that apply and/or enter "Other" description)

- ☐ Fatigue
- ☐ Cramping
- ☐ Pain
- ☐ Other: _____

_____

Describe any other symptoms noted by the subject during the treadmill test: (check all that apply and/or enter "Other" description)

- ☐ Chest pain
- ☐ Shortness of breath
- ☐ Dizziness
- ☐ Joint Pain
- ☐ Other: _____

Index Leg: ☐ R ☐ L ☐ Both (If "Both" checked, patient does not qualify for study)

Comments:

Person(s) responsible for conducting the treadmill test:

_____

Entered to eCRF ☐ Initials _____

FORM NO. CND030					
Acrostic Identifier:					
Study ID:					
Date source form completed (mm/dd/yyyy): _____/_____/_____					
ABI / TBI - *Baseline, Month 3, Month 6*					
Date of Assessment (mm/dd/yyyy): _____/_____/_____			Visit Type:		
Measurement Collected:	☐ ABI	☐ TBI	*Baseline selected based on calculated Resting ABI Measurements (see below); M3 & M6 - same as Baseline.*		

Pre-Exercise ABI Pressure Readings			Check this box if non-compressible vessels ☐			
Time (hhmm 24-hour clock): __ __ __ __			*Shaded fields are filled in by ABI eCRF programming*			
all pressures are Doppler SBP (mmHg)	1st Reading	2nd Reading	Unable to Obtain	Average Reading	*These fields are determined based on "Readings"*	
Right Arm Pressure	__ __ __	__ __ __	☐	__ __ __	Highest Average Arm:	Highest Average Arm Reading
Left Arm Pressure	__ __ __	__ __ __	☐	__ __ __	Right ☐ Left ☐	__ __ __
Right DP Ankle Pressure	__ __ __	__ __ __	☐	__ __ __	Right Highest Average ankle:	Highest Average R-ankle Reading
Right PT Ankle Pressure	__ __ __	__ __ __	☐	__ __ __	DP ☐ PT ☐	__ __ __
Left DP Ankle Pressure	__ __ __	__ __ __	☐	__ __ __	Left Highest Average ankle:	Highest Average L-ankle Reading
Left PT Ankle Pressure	__ __ __	__ __ __	☐	__ __ __	DP ☐ PT ☐	__ __ __
Pre-Exercise ABI Measurements *(Calculated by Database)*						
Resting Right Leg ABI	__ . __ __ __		If the ***index leg*** Resting Leg ABI (R or L) is <0.9, select ABI. If the ***index leg*** Resting Leg ABI (R or L) is >1.3, or documented as unable to obtain due to non-compressible vessels, select TBI. If the ***index leg*** 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.						

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

FORM NO. CND030	
Acrostic Identifier:	
Study ID:	
Date source form completed (mm/dd/yyyy): _____/_____/_____	

ABI / TBI - *Baseline, Month 3, Month 6*

Post-Exercise Pressure Readings (ABI only)			
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.			Post-Exercise Measurements (Pressure Readings)
Highest Average ARM from RESTING ABI:	Right ☐	Left ☐	__ __ __
Highest Average Right-ANKLE from RESTING ABI:	DP ☐	PT ☐	__ __ __
Highest Average Left-ANKLE from RESTING ABI:	DP ☐	PT ☐	__ __ __

Were arm and ankle pressures obtained within 2 minutes of the treadmill testing? ☐ Yes ☐ 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? ☐ Yes ☐ No ☐ Pressure was detected at first attempt

If Yes, how many minutes after the treadmill test did the pressures return? __ __ minutes

Post-Exercise ABI Measurements *(Calculated by Database)*			
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