SCREENING FORM

Demographics

Complete Questions 1-4 for all patients who are screened.

	inprote Edestrone 1 1 for an patients who are a	
1.	Gender:	☐ Male ☐ Female
2.	Age in years:	years
3.	Ethnicity:	☐ Hispanic or Latino ☐ NOT Hispanic or Latino ☐ Unknown
4.	Race: Select ALL that apply.	NOTE: If the race(s) cannot be obtained from the patient, the patient's family, or from a source document, select "not reported".
A.	American Indian or Alaskan Native	
В.	Asian	
Ċ	White	
D.	Black or African Native	
E.	Native Hawaiian or Pacific Islander	
F.	Not reported	

Inclusion/Exclusion Criteria

To be completed on all patients who are screened.

		bleted on all patients who are screened.		
1.		select yes or no to indicate whether patient the following inclusion criteria?		
	1)	Participant must have at least five minutes of chest pain or equivalent (chest tightness; pain radiating to left, right, or both arms or shoulders, back, neck, epigastrium, jaw/throat; or unexplained shortness of breath, syncope/presyncope, generalized weakness, nausea, or vomiting thought to be of cardiac origin) at rest or during exercise within 24 hours of ED presentation, warranting further risk stratification, as determined by an ED attending.	Yes	□ No
	2)	Participant is able to provide written Informed Consent	☐ Yes	∐ No
	3)	Participant is < 75 years of age, but ≥ 40 years of age	☐ Yes	☐ No
	4)	Participant is able to perform a breath hold of at least 10 seconds	☐ Yes	☐ No
	5)	Participant is in sinus rhythm	☐ Yes	□ No
2.		select yes or no to indicate whether patient the following exclusion criteria		
	1)	New diagnostic ischemic ECG changes		
ST-segment elevation or depression > 1 mm or T-wave inversion > 4 mm in two or more anatomically adjacent leads or left bundle branch block				□ No

2)	Documented or self-reported history of CAD					
	cutaneous coronary interventions [PCIs], coronary	☐ Yes	□ No			
	artery bypass graft [CABG], known significant coronary stenosis [>50%]					
	Greater than 6 hours since presentation to ED to time	☐ Yes	□ No			
	of consent					
4)	BMI $>40 \text{ kg/m}^2$	☐ Yes	∐ No			
5)	Impaired renal function, as defined by local standard of care, for example, measured serum creatinine >1.5 mg/dL	☐ Yes	□ No			
6)	Markedly elevated troponin, as defined by local standard of care	Yes	□ No			
7)	Hemodynamically or clinically unstable condition (BP systolic < 80 mm Hg, atrial or ventricular arrhythmias, persistent chest pain despite adequate therapy)	☐ Yes	□ No			
8)	Known allergy to iodinated contrast agent	☐ Yes	□ No			
9)	Currently symptomatic asthma	☐ Yes	□ No			
,	Documented or self-reported cocaine use within the	□ Vaa				
10)	past 48 hours (acute)	∐ Yes	∐ No			
11)	On Metformin therapy and unable or unwilling to discontinue for 48 hours after the CT scan	Yes	□ No			
12)	Contraindication to beta blockers (taking daily antiasthmatic medication): This exclusion only applies to patients with a heart rate > 65 bpm at sites using a non-dual source CT scanner	☐ Yes	□ No			
13)	13) Participant with no telephone or cellphone number					
14)	Participant with positive pregnancy test within 24 hours					
_	prior to CT scan.	☐ Yes	□ No			
·	<u>For woman of childbearing potential,</u> defined as: < 2 years of menopause in the absence of hysterectomy or tubal ligation.					
	15) Participant unwilling to provide written informed consent.					
	CUIISCIII.	1				
ED Eva	aluation Timeline					
	ED Presentation (mm/dd/yyyy):					
	ED Presentation (hh:mm):					
1	Initial ED Evaluation					
	d/yyyy): f Completion of Initial ED Evaluation					
(hh:mn	•					
1	time point at which the ED					
physician p	uts in the 1st set of orders.)					

Randomization & Consent

1.	Date of Consent (mm/dd/yyyy):	
2.	Time of Consent (hh:mm):	
3.	Was the patient randomized?	☐ Yes ☐ No* If yes, ☐ SOC arm ☐ Interventional arm
		Randomization number If no, reason: markedly positive troponin positive pregnancy test patient withdrew consent other, specify
4.	Date of Randomization (mm/dd/yyyy):	
5.	Time of Randomization (hh:mm):	

MEDICAL HISTORY FORM

Cardiac Risk Factors and Medications

1.	Hypertension	│
2.	Diabetes mellitus	☐ None ☐ Insulin requiring ☐ Non-insulin ☐ Not Reported
3.	Hypercholesterolemia/hyperlipidemia	Yes No Not Reported
4.	Cocaine use	☐ Never ☐ Former ☐ Recent (last use >48 hours)
5.	Tobacco use	☐ Never ☐ Former ☐ Current ☐ Not Reported
6.	First degree relative with CAD/ACS/AMI: (male < 55 yrs, female < 65 yrs)	☐ Yes ☐ No ☐ Not Reported
7.	Home medications:	
	a. ACE-inhibitors/ARB	☐ Yes ☐ No
	b. Aspirin	Yes No
	c. Nitrates	Yes No
	d. Beta-blockers	☐ Yes ☐ No
	e. Calcium channel blocker	Yes No
	f. Statins	☐ Yes ☐ No
	g. Niacin/fibrates	Yes No
	h. Insulin	Yes No
	 i. Oral hypoglycemics 	Yes No

Medical History

|--|

2. Peripheral vascular diseas	se		Yes	☐ No	■ Not Reporte
3. Chronic lung disease/COF			Yes	☐ No	Not Reporte
4. Cerebrovascular event (st	roke)	L	_ Yes	∐ No	
Pain Characteristic Patient reported data:	s/Symp	tom	ıs		
1. Chief Complaint		[Epigastr Arm/Jav Shortne Other:	ic Pain v/Shoulder ss of Breat	
2. Most recent Episode		1	Date (mm/ Time (hh:n Duration (r	nm)	
Data collected by CRC from ED cl 1. Weight: 2. Height:	hart.			lbs inche	
3. Resting heart rate:4. Systolic BP:			bpm mml		
5. Diastolic BP:				mml	~
6. Presence of rales?		E R	Yes eported	☐ No	Not
Data collected from ED record. Some services. 1. Aspirin 2. Nitrates 3. Beta blocker 4. Morphine		t appl	y. 		
5. Heparin/ Low molecular v heparin/ Fragmin/ Loven6. Plavix					
Laboratory Results Data collected from ED record. Test Date	Time	, -	Result		Not done
Creatining					30110

mg/dL

Creatinine (initial)

Creatinine (2 nd)					mg/dL		
Creatinine (3rd)	•			mg/dL			
CK-MB (initial)				ug/ml			
CK-MB (2 nd)					ug/ml		
CK-MB (3 rd)					ug/ml		
D-Dimer					ng/ml		
Tropo Test	rin Value	PS Date	Tir	me	Result	Range	Not done
Troponi n (initial)	classification T				ug/ml	Normal Enter Range: Borderline Enter Range: Elevated Enter Range:	
Troponi n (2 nd)	T				ug/ml	☐ Normal Enter Range: ☐ Borderline Enter Range: ☐ Elevated Enter Range:	
Troponi n (3 rd)	T				ug/ml	☐ Normal Enter Range: ☐ Borderline Enter Range: ☐ Elevated Enter Range:	
Biomarker Testing							
Did the patient consent to biomarker testing?							
If yes,							
Draw #1: Was blood collected and stored? If less than 3 tubes collected, fill out protocol deviation form. Yes \sum No							
Date (mm/dd/yyyy): Time (hh:mm):							

Red tube specimen ID no How many daughter tubes?	
3 0	
Purple tube specimen ID no How many daughter tubes?	
Green tube specimen ID no How many daughter tubes?	
	less than 3 tubes collected, fill out protocol deviation form.
Date (mm/dd/yyyy): Time (hh:mm):	
Red tube specimen ID no How many daughter tubes?	
Purple tube specimen ID no How many daughter tubes?	
	less than 3 tubes collected, fill out protocol deviation form.
Yes No	
Date (mm/dd/yyyy):	
Red tube specimen ID no How many daughter tubes?	
Purple tube specimen ID no How many daughter tubes?	
Green tube specimen ID no How many daughter tubes?	
ECC FORM	
ECG FORM	
Initial 12-Lead ECG Interpre	etation
Information entered into eCRF by CRC.	
Date of initial ECG (mm/dd/yyyy):	
2. Time of initial ECG (hh:mm):	
3. ECG (electronic read)	HR bpm QTms QTcms

CT FORM

CCTA Technical Assessment

To be entered into eCRF by CRC.

Was CCTA performed For interventional arms of not performed.	□ v □ N.
For interventional arm, If not performed	Yes No
	If no, indicate why not done: Definite ACS (positive troponin, ECG changes)
For interventional arm: If not performed, please complete protocol deviation form or	Contrast extravasation
protocol violation form	Arrhythmias
	Claustrophobia
	Anaphylaxis
	ED physician decision
	Patient refusal/withdrawal
	Equipment failure
	Other:
A. Record Scanner	Manufacturer: Siemens
Manufacturer/Model	☐ GE
	L Philips
	☐ Other
	Model: Somatom Sensation 64
	Lightspeed 64
	☐ Lightspeed VCT☐ Dual Source
	☐ Dual Source ☐ Flash
	☐ Other
B. Hybrid Imaging (SPECT or PET)	☐ Yes ☐ No
C. Time CT ordered (hh:mm)	
D. Time CT performed (hh:mm)	
E. Time of CT interpretation	
(hh:mm)	
2. Calcium Scan	□ v _{aa} □ Na
If no, give reason and fill out protocol violation form	∐ Yes ∐ No
Violation form	
3. CTA	☐ Yes ☐ No
3. CTA 4. Intra CCTA vitals:	☐ Yes ☐ No
	bpm
4. Intra CCTA vitals:	
4. Intra CCTA vitals: Average HR during scan:	bpm Yes No Yes No
Intra CCTA vitals: Average HR during scan: Pre-procedure medications:	bpm Yes No Yes No If yes, Metoprolol
4. Intra CCTA vitals: Average HR during scan:	bpm Yes No Yes No If yes, Metoprolol Other
Intra CCTA vitals: Average HR during scan: Pre-procedure medications:	bpm Yes No Yes No If yes, Metoprolol Other dose: mg
Intra CCTA vitals: Average HR during scan: Pre-procedure medications:	bpm Yes No Yes No If yes, Metoprolol Other dose: mg Yes No
Intra CCTA vitals: Average HR during scan: Pre-procedure medications:	bpm Yes No Yes No If yes, Metoprolol Other dose: mg Yes No Metoprolol
4. Intra CCTA vitals: Average HR during scan: 5. Pre-procedure medications: a. Beta blocker IV	bpm Yes No Yes No If yes, Metoprolol Other dose: mg Yes No Metoprolol Atenolol
4. Intra CCTA vitals: Average HR during scan: 5. Pre-procedure medications: a. Beta blocker IV	bpm Yes No Yes No If yes, Metoprolol Other dose: mg Yes No Metoprolol

6. Contrast agent: a. concentration mg iodine per ml	☐ Isovue		
7. Completion of the CT scan Yes			
8. Prospectively gated/triggered cardiac C	ΓA scan		
9. Retrospectively gated cardiac CTA scan			
10. Dose Length Product of CTA only:	mGY cm		
11. Total Dose Length Product	mGY cm		
12. CTDI Volume of CTA	mGy		
To be completed by CT reader with signature no entered on form by CRC. 1. Reading physician ID: (Please have CT			
Reader initial paper CRF)			
2. Calcium Score			
3. Coronary CTA			
out the protocol violation form.	of stenosis. If level of stenosis equals stent, please fill		
a. Left Main	□normal 0% □1-49% (non-significant/mild or minor) □ 50-99% (significant/severe) □ 100% (occluded) □indeterminate □ stent**		
b. LAD (any) normal 0% 1-49% (non-significant/mild o minor) 50-69% (moderate) 70-99% (significant/severe) 100% (occlu indeterminate steet*			
c. LCX (any)	□normal 0% □1-49% (non-significant/mild or minor) □50-69% (moderate) □70-99% (significant/severe) □ 100% (occluded) □indeterminate □ stent**		
d. RCA (any)	☐normal 0% ☐1-49% (non-significant/mild or minor) ☐50-69% (moderate) ☐ 70-99% (significant/severe) ☐ 100% (occluded) ☐ indeterminate ☐ stent**		
4. Overall study quality:	Interpretable:		

	Uninterpretable:			
5. LV functional analysis performed:	Yes No			
	Global LV function			
6. If retrospectively gated, was tube				
modulation technique or a similar	☐ Yes ☐ No			
radiation safety technique used?				
7. Incidental Findings	Yes No If yes, mark all that apply: Coronary anomaly Cardiac finding If yes, specify Pulmonary nodules requiring follow-up Pulmonary Embolism Pneumonia Aortic Aneurysm Other If yes, specify, Requires follow up imaging Yes No			
**If stent is present, please check the medical record (MR). If evidence of a stent is documented in the MR, fill out the protocol violation form.				
<u> </u>				

DIAGNOSTIC TESTING FORM

Nuclear Imaging

1. Was nuc	clear imaging done?	☐Yes ☐No
	e the initials of the n who reported it?	
3. Date/tir	ne test ordered:	Date (mm/dd/yyyy): Time (hh:mm):
4. Date/time test was performed: Date (mm/dd/yyyy) Time (hh:mm):		Date (mm/dd/yyyy): Time (hh:mm):
5. Date/tir	ne of test interpretation:	Date (mm/dd/yyyy): Time (hh:mm):
6. Modality	/ :	☐ Rest ☐ Stress ☐ Rest & Stress If stress, select one of the following: ☐ ETT (go to qs.7) ☐ Pharmacologic (go to qs. 9)

7.	☐Bruce	
I F F T T	☐ Modified Bruce Time to end of exercise	
If ETT,	☐Naughton☐Supine Bicycle	minsec METS
	Upright Bicycle	%MPHR
	oprigitt bicycle	70IVII T IIX
8. ECG changes meeting criteria for	□Yes □No	
ischemia?	If yes, specify changes:	
	o ST depression	□Yes □No
		nu <u>m_</u> depression?mm
	o ST elevation	□Yes □No
		num elevation?mm
	o Ventricular arrhythmias	
	o Other	☐Yes ☐No, if yes, specify
10 15	Dobutamine	
10. If pharmacological, list the agent used:	□Dipyridamole	
useu.	Adenosine	
	Regadenoson	
11. Rest protocol tracer:	Tankan akii uus	
	Technetium Tetrafosmin	
administered activity /unit of	Thallium	
activity	(Mega Bq/millicuries)	
12. Stress Protocol tracer	(Moga Bay Milliour 100)	
	☐ Technetium	
	□ Tetrafosmin	
administered activity /unit of	☐ Thallium	
activity	(Mega Bq/millicuries)	
13. Was a Reinjection performed?	D Vac D Na	
	Yes No	
	If yes, fill out the following: Tracer	
	Technetium	
	Tetrafosmin	
administered activity /unit of	Thallium	
activity	(Mega Bq/millicuries)	
	☐Yes ☐No	
14. Was a Rubidium test performed?	If yes,	
rest	administered activity /unit of acti	vity(Mega
stress	Bq/millicuries)	with a Maga
	administered activity /unit of acti Bg/millicuries)	vity(iviega
	<u> </u>	leted Performed but not
	completed	s.roimod bat not
15 Completion of Protocol	Baseline Heart rate bpm	
15. Completion of Protocol	Peak Heart Rate bpr	
	Systolic Blood Pressure at rest mmHg	
	Diastolic Blood Pressure at rest _	
	Systolic Blood Pressure at peak s	
	Diastolic Blood Pressure at peak	stressmmHq

	Reached target HR?* Yes No NA If no, was it converted to pharmacologic? Yes No If yes, choose the agent used: Dobutamine Dipyridamole Adenosine Regadenoson Did the patient develop symptoms of possible CAD (including CP, SOB) Yes No equivocal (if the answer is yes or equivocal, go to qs 15)
16. If there were symptoms of possible CAD, enlist any other symptoms perceived by the patient.	Chest Pain
17. Was the perfusion in the anterior/apical myocardial territory normal?	□Yes □No
18. Was the perfusion in the lateral myocardial territory normal?	□Yes □No
19. Was the perfusion in the infero- posterior myocardial territory normal?	□Yes □No
20. Resting gated LVEF	Not done EF % ☐Normal ☐Abnormal
21. Post stress gated LVEF	EF % Normal Abnormal
22. Transient Ischemic Dilatation	Yes No Not Mentioned
23. Was additional nuclear imaging performed?	□Yes □No

Stress Echocardiogram

1. Was a stress echocardiogram performed?	☐Yes ☐No	
2. What are the initials of the physician who reported it?		
3. Date/time test ordered:	Date (mm/dd/yyyy): Time (hh:mm):	
4. Date/time test performed:	Date (mm/dd/yyyy): Time (hh:mm):	
5. Date/time of test interpretation:	Date (mm/dd/yyyy): Time (hh:mm):	
6. Modality:	Select one of the following: Exercise Dobutamine Other	
7. If Exercise:	□ Bruce □ Modified Bruce □ Naughton □ Supine Bicycle □ Upright Bicycle Time to end of exercise minsec METS %MPHR	
8. If Dobutamine:	Maximum dobutamine dose given:mcg/kg/min Atropine given?:	
9. ECG changes:	Yes No If yes, specify changes: Yes ST depression Yes If yes, what is the maximum depression?mm ST elevation Yes If yes, what is the maximum elevation?mm Ventricular arrhythmias Yes No Other Yes No	
10. Completion of protocol:	Not done ☐ Done and completed ☐ Performed but not completed Baseline Heart Rate bpm (3 digits) Peak Heart Rate bpm Systolic Blood Pressure at rest mmHg Diastolic Blood Pressure at rest mmHg Systolic Blood Pressure at peak stress mmHg Diastolic Blood Pressure at peak stress mmHg Diastolic Blood Pressure at peak stress mmHg Reached target HR? ☐ Yes ☐ No If no, was it converted to pharmacologic? ☐ Yes ☐ No If yes, choose the agent used:	

Tr.	
	□ Dobutamine □ Dipyridamole □ Adenosine □ Regadenoson Did the patient develop symptoms of possible CAD (including CP, SOB) □ Yes □ No □ equivocal (if the answer is yes or equivocal, go to qs 11)
11. If there were symptoms of possible CAD, enlist any other symptoms perceived by the patient.	Chest Pain
12. Was the wall motion in the anterior/apical segment normal on stress?	□Yes □No
13. Was the wall motion in the lateral segment normal on stress?	□Yes □No
14. Was the wall motion in the inferoposterior segment normal on stress?	□Yes □No
15. Resting LVEF	EF%
16. Stress LVEF	EF%
17. LV Dilatation at Peak Stress	☐Yes ☐No ☐Not Mentioned
18. ECHO Results:	□Normal □Abnormal If abnormal, specify: □ Inducible ischemia □ MI/scar (no ischemia) □ Both

Was another Stress Echocardiogram done?	□No	
Transthoracic Echocardiogram (rest) To be entered on form by CRC		
Was a resting transthoracic echocardiogram performed?	□Yes □No	
2. What are the initials of the physician where performed the test?	no	
3. Date/time test ordered:	Date (mm/dd/yyyy): Time (hh:mm):	
4. Date/time test performed:	Date (mm/dd/yyyy): Time (hh:mm):	
5. Date/time of test interpretation:	Date (mm/dd/yyyy): Time (hh:mm):	
6. Was the wall motion in the anterior/apical segment normal?	□Yes □No	
7. Was the wall motion in the lateral segment normal?	□Yes □No	
8. Was the wall motion in the infero- posterior segment normal?	□Yes □No	
9. LV function (Ejection fraction %)	%	
10. Results:	☐Normal ☐Abnormal If abnormal, specify:	
11. Was a resting transthoracic echocardiogram done again?	□Yes □No	
Exercise ECG Stress Test (Non-imaging only) To be entered on form by CRC.		
Was an exercise ECG stress test performed?	□Yes □No	
2. What are the initials of the physician who performed the test?		
3. Date/time test ordered:	Date (mm/dd/yyyy): Time (hh:mm):	
4. Date/time test performed:	Date (mm/dd/yyyy): Time (hh:mm):	

5. Date/time of test interpretation:	Date (mm/dd/yyyy): Time (hh:mm):
6. Type of Exercise protocol	☐ Bruce ☐ Modified Bruce ☐ Naughton ☐ Supine Bicycle ☐ Upright Bicycle
7. Functional Capacity	Time to end of Treadmillminsec METS %MPHR
8. Completed protocol?	Not done Done and completed Performed but not completed Peak Heart Rate bpm (3 digits) Baseline Heart Rate bpm Reached target HR? Yes No NA If no, was it converted to pharmacologic? Yes No If yes, choose the agent used: Dobutamine Dipyridamole Adenosine Adenosine Regadenoson Symptoms of possible CAD (including CP, SOB)
9. If there were symptoms of possible CAD, enlist any other symptoms perceived by the patient.	Chest Pain
10. Results:	□ Negative
11. Was exercise ECG stress test done again?	□Yes □No

Cardiac Catheterization

To be entered by the CRC

1. Was Cardiac Catheterization done?	□Yes □No
2. Initials of physician who interpreted test:	
3. Date/time test ordered:	Date (mm/dd/yyyy): Time (hh:mm):
4. Date/time test performed:	Date (mm/dd/yyyy): Time (hh:mm):
5. Date/time of test interpretation:	Date (mm/dd/yyyy): <u>Time (hh:mm)</u> :
6. Were there any complications to the procedure (as per cath lab ACC/NCDR	∐Yes ∐No
instruction)?	If yes, fill out adverse event form.
7. Mark the appropriate box to indicate the	
a. Left Main	☐ normal 0% ☐ 1-49% (non-significant/mild or minor) ☐ 50-99% (significant/severe) ☐ 100% (occluded) ☐ indeterminate ☐ stent note:
b. LAD (any)	☐ normal 0% ☐ 1-49% (non-significant/mild or minor) ☐ 50-69% (moderate) ☐ 70-99% (significant/severe) ☐ 100% (occluded) ☐ indeterminate ☐ stent note:
c. LCX (any)	□normal 0% □1-49% (non-significant/mild or minor) □50-69% (moderate) □70-99% (significant/severe) □ 100% (occluded) □indeterminate □ stent note: □
d. RCA (any)	☐normal 0% ☐1-49% (non-significant/mild or minor) ☐50-69% (moderate) ☐ 70-99% (significant/severe) ☐ 100% (occluded) ☐indeterminate ☐ stent note:
e. LV Gram	□ Normal □ Abnormal
8. Did subject undergo revascularization?	☐ Yes ☐ No If yes, type of revascularization: ☐ PCI ☐ LM ☐ Yes ☐ No ☐ LAD ☐ Yes ☐ No ☐ LCX ☐ Yes ☐ No ☐ RCA ☐ Yes ☐ No ☐ CABG
9. Radiation Exposure	Fluoro time Min/sec Cine runs Number Radiation Dose
10. Cardiac Catheterization done again?	□Yes □No

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PATIENT DISCHARGE FORMPatient Discharge Information

<u>U</u>	
1. Disposition:	□ Direct ED Discharge □ Observational Unit admission □ Hospital admission □ Died prior to ED discharge; (If so, fill out SAE form) □ Date of death (mm/dd/yyyy): □ Time of death (hh:mm): □ Left against medical advice (If so, fill out Protocol Deviation form) □ Other, specify:
2. Date/time of index hospital discharge:	Date (mm/dd/yyyy): Time (hh:mm):
3. Was the subject admitted to the hospital? If so where?	
4. Primary discharge diagnosis (Choose One):	□ Noncardiac chest pain □ Non coronary cardiac chest pain □ Acute Coronary Syndrome □ Cardiac chest pain not meeting Acute Coronary Syndrome
5. If Non cardiac Chest Pain, (Choose one):	Pulmonary embolism Pneumonia GERD Gastrointestinal Musculoskeletal Aortic dissection Non cardiac CP without clear alternate diagnosis Other, specify
6. If, Non coronary cardiac chest pain, (Choose One):	Pericarditis/Myocarditis Valvular Cardiomyopathy Other
7. If Acute Coronary Syndrome, (Choose One):	Myocardial Infarction (defined as 1 and 2) 1. Anginal equivalent > 10 minutes AND 2. Typical rise and fall of cardiac biomarkers

	rest or in an accelerating pattern
	At least one objective sign :
	a. New ST-segment changes
	b. New TWI
	c. Positive stress-test with imaging
	showing ischemia
	 d. Positive stress test without
	imaging resulting in increased
	anginal medication
	e. Cath >70% stenosis or thrombus
	f. CT angiography with >50%
	stenosis and LV dysfunction or
	>70% stenosis
	Stroke Yes No
8. Did the subject have any peri-procedural	Bleeding ☐Yes ☐No
complications?	Renal failure Yes No
!	Ananhylaxis TVes TNo

48-72 HOUR FOLLOW UP FORM

48-72 Hour Follow UpComplete only for patients discharged within 24 hours of ED presentation.

	W	Yes No NA
1.	Was the 48-72 hour follow-up call completed?	If No, Did the subject withdraw from the study? Yes No
		If yes, reason:
2.	Date of contact (mm/dd/yyyy):	
	Time of contact (hh:mm):	
4.	How many attempts were made to reach the	□ 1 □ 2 □ 3 □ 4 □ 5 □ >5
	patient?	
		∐Yes
5	Did subject die?* If yes, fill out SAE form.	If yes, death reported how?
٥.	bid subject die. If yes, fill out one form.	Relative
		SSDI
		Medical record
	a. Date of death (mm/dd/yyyy):	
	b. Time of death (hh:mm):	
		CV death due to coronary heart disease
	c. Cause of death:	CV death not directly due to coronary heart disease
		☐ Non CV_death
		Other
6.	Did subject have recurrence of chest pain or	☐Yes ☐No
	anginal equivalent?	If yes, provide, duration of longest episode:
7. Did subject return to ED?	Did cubicat rature to ED2	□Yes □No
	Dia subject letaili to LD:	If yes, complete supplement form
8.	Did subject return to OPD (since index	☐Yes ☐No
	hospitalization/last contact)?	If yes, complete supplement form
9. V	Was the patient admitted to the hospital?	☐Yes ☐No
		If yes, complete supplement form
10	. Was an ongoing hospitalization prolonged for	☐Yes ☐No
	ischemic signs/symptoms?	If yes, complete supplement form
11.	. Did subject have ECG changes (since index	Yes * No
	hospitalization/last contact)? *	If Yes, complete supplement form

12. Were Cardiac biomarkers obtained (since index hospitalization/last contact)?	☐Yes ☐No If Yes, complete supplement form
13. Was a stress test performed?* If yes, fill out SAE form	☐Yes * ☐No If yes, complete supplement form and provide report.
14. Was a coronary angiogram performed?* If positive, fill out SAE form.	☐Yes* ☐No If yes, complete supplement form and provide report.
15. Was a PCI performed?* If yes, fill out SAE form.	☐Yes * ☐No If yes, complete supplement form and provide report.
16. Did subject undergo heart revascularization?	☐Yes * ☐No
*If yes, fill out SAE form	If yes, complete supplement form and provide report.
17. Did the subject have any peri-procedural	☐Yes * ☐No
complications? * If yes, fill out SAE form	If yes, complete supplement form and provide report.
18. What source documents have been provided by site?	□ Discharge summary □ Exercise testing report □ Death note, certificate □ Cardiac Cath/PCI report □ CABG report □ Other, specify □ ECG, during & after event

48-72 HOUR FOLLOW UP SUPPLEMENT FORM

1	Was the 48-72 hour follow-up call completed?	☐ Yes ☐ No ☐ NA If No, Did the subject withdraw from the study? ☐ Yes ☐ No
١.	was the 40-72 flour follow-up can completed:	If yes, reason:
	Data of contact (non-/dd/non-)	II yes, reason
	Date of contact (mm/dd/yyyy):	
3.	Time of contact (hh:mm):	
4.	How many attempts were made to reach the patient?	□ 1 □ 2 □ 3 □ 4 □ 5 □ >5
		☐Yes ☐No
l _	D. I . I . O. IC	If yes, death reported how?
5.	Did subject die?* If yes, fill out SAE form.	Relative
		□ SSDI
		Medical record
	a. Date of death (mm/dd/yyyy):	iwedical record
	. 3333:	
	b. Time of death (hh:mm):	
		CV death due to coronary heart disease
	c. Cause of death:	CV death not directly due to coronary heart disease
	c. cause of death.	│
		Other
6.	Did subject have recurrence of chest pain or	☐Yes ☐No
	anginal equivalent?	If yes, provide, duration of longest episode:
		☐Yes ☐No
		If yes,
7.	Did subject return to ED?	a. Date of return (mm/dd/yyyy):
	-	b. Time of return (hh:mm):
		c. Institution:

	d. Reason:
	Recurrent chest pain*
	Other, specify
	*Fill out SAE form
	Tim out one form
	Discharged?
	Yes No
	If yes,
	e. Date (mm/dd/yyyy):
	f. Time (hh:mm):
	☐Yes ☐No
	If yes,
	I = -
	a. Date of return (mm/dd/yyyy):
	b. Time of return (hh:mm):c. Institution:
	c. Institution: d. Reason:
O Did subject waterms to ODD (since index	Recurrent chest pain*
8. Did subject return to OPD (since index	Other, specify
hospitalization/last contact)?	*Fill out SAE form
	If yes
	If yes,
	Discharged? ☐Yes ☐No
	<u> </u>
	If yes,
	e. Date (mm/dd/yyyy): f. Time (hh:mm):
	Yes No
	If yes,
	a. Date of admission (mm/dd/yyyy):
	b. Institution:
	c. Reason:
	Recurrent chest pain*
9. Was the patient admitted to the hospital?	Other, specify
7. Was the patient admitted to the hospital:	*Fill out SAE form
	Discharged?
	Yes No
	If yes,
	d. Date (mm/dd/yyyy):
	e. Time (hh:mm):
	☐Yes ☐No
10. Was an ongoing hospitalization prolonged for	If yes,
ischemic signs/symptoms?	a. Date of admission (mm/dd/yyyy):
3 , 1	b. Institution:
11. Did subject have ECG changes (since index	Yes * No
hospitalization/last contact)? *	If Yes, check appropriate boxes below and fill out SAE form:
•	☐ ST elevation >1mm
	ST depression >1mm
	TWI >1mm
12. Were Cardiac biomarkers obtained (since index	□Yes □No
hospitalization/last contact)?	
If yes,	
Peak cTn result?	☐Yes ☐No

	Provide peak cTn result:
	Provide cTn units:
	Provide cTn ULN:
Peak CK-MB result?	☐Yes ☐No
	Provide peak CK-MB result:
	Provide CK-MB units:
	Provide CK-MB ULN:
13. Was a stress test performed?* If yes, fill out SAE	☐Yes * ☐No
form	If yes, provide report.
	If yes, was it ETT or nuclear imaging?
	If yes, you will need to fill out the ETT or Nuclear imaging
	questions.
14. Was a coronary angiogram performed?* If	☐Yes* ☐No
positive, fill out SAE form.	If yes, you will need to fill out the coronary angiogram
	questions and provide report.
15. Was a PCI performed?* If yes, fill out SAE form.	☐Yes * ☐No
	If yes, you will need to fill out the PCI questions and
	provide report.
	☐Yes * ☐No
	If yes, provide report.
16. Did subject undergo heart revascularization?	If yes, select method of revascularization:
*If yes, fill out SAE form	□CABG
	☐ Stent
	Unknown
	Stroke Yes No
17. Did the subject have any peri-procedural	Bleeding Yes No
complications? * If yes, fill out SAE form	Renal failure Yes No
	AnaphylaxisYesNo
	□ Discharge summary □ Exercise testing report
18. What source documents have been provided by	Death note, certificate Cardiac Cath/PCI report
site?	Cardiology consultation note CABG report
31.01	☐Biomarker report ☐Other, specify
	ECG, during & after event
28 DAY FOLLOW UP FORM	Λ
	•
	☐ Yes ☐ No
1. Was the 28 day follow-up call completed?	If No, Did the subject withdraw from the study? Yes No
	If yes, reason:
2. Date of contact (mm/dd/yyyy)	
3. How many attempts were made to reach the	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ >5
patient?	
	☐Yes ☐No
	If yes, death reported how?
4. Did subject die (since index	Relative
hospitalization/last contact)?	SSDI
	Medical record
	If yes, provide death note, certificate.

d. Date of death:

e. Time of death (hh:mm):	
f. Cause of death:	CV death due to coronary heart disease CV death not directly due to coronary heart disease Non CV death Other
4. Did subject have recurrence of chest pain or anginal equivalent (since index hospitalization/last contact)?	☐Yes ☐No If yes, provide, duration of longest episode:
5. Did subject return to ED (since index hospitalization/last contact)?	☐Yes ☐No If yes, complete supplement form and provide report
6. Did subject return to OPD (since index hospitalization/last contact)?	Yes No If yes, complete supplement form and provide report
7. Was the patient admitted to the hospital (since index hospitalization/last contact)?	Yes No If yes, complete supplement form and provide report
8. Was an ongoing hospitalization prolonged for ischemic signs/symptoms?	Yes No If yes, complete supplement form and provide report
9. Did the subject have ECG changes (since index hospitalization/last contact)?	Yes No If Yes, complete supplement form and provide a copy of the ECG
10. Were Cardiac biomarkers obtained (since index hospitalization/last contact)?	☐Yes ☐No If yes, complete supplement form
11. Was a stress test performed (since index hospitalization/last contact)?	☐Yes ☐No If yes, complete supplement form and provide report
12. Was a coronary angiogram performed (since index hospitalization/last contact)?	☐Yes ☐No If yes, complete supplement form and provide report
13. Was a PCI performed (since index hospitalization/last contact)?	☐Yes ☐No If yes, complete supplement form and provide report
14. Did subject undergo heart revascularization (since index hospitalization/last contact)?	☐Yes ☐No If yes, complete supplement form and provide report
15. What source documents have been provided by site?	□ Discharge summary □ Exercise testing report □ Cardiac Cath/PCI report □ CABG report □ CABG report □ Other, specify: □ ECG, during & after event □ Discharge testing report □ Cardiac Cath/PCI report □ CABG report □ Other, specify: □ ECG, during & after event

28 DAY FOLLOW UP SUPPLEMENT FORM

1.	Was the 28 day follow-up call completed?	☐ Yes ☐ No If No, Did the subject withdraw from the study? ☐ Yes ☐ No If yes, reason:
2.	Date of contact (mm/dd/yyyy)	
3.	How many attempts were made to reach the patient?	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ >5
4.	Did subject die (since index	☐Yes ☐No
İ	hospitalization/last contact)?	If yes, death reported how?

	Relative
	SSDI Medical record
	If yes, provide death note, certificate.
g. Date of death:	in yes, provide death note, certificate.
h. Time of death (hh:mm):	
,	CV death due to coronary heart disease
: Course of death.	CV death not directly due to coronary heart disease
i. Cause of death:	☐ Non CV death
	Other
4. Did subject have recurrence of chest pain or	□Yes □No
anginal equivalent (since index	
hospitalization/last contact)?	If yes, provide, duration of longest episode:
	☐Yes ☐No
	If yes,
	a. Date of return (mm/dd/yyyy):b. Time of return (hh:mm):
	c. Institution:
	d. Reason:
5. Did subject return to ED (since index	Recurrent chest pain
hospitalization/last contact)?	Other, specify
,	If yes,
	Discharged?
	□Yes □No
	If yes, please provide a copy of the report
	e. Date (mm/dd/yyyy):
	f. Time (hh:mm):
	☐Yes ☐No
	If yes,
	a. Date of return (mm/dd/yyyy):b. Time of return (hh:mm):
6. Did subject return to OPD (since index	c. Institution:
hospitalization/last contact)?	d. Reason:
nospitalization, last contacty.	Recurrent chest pain*
	Other, specify
	*Please provide a copy of the report
	☐Yes ☐No
	If yes,
	a. Date of admission (mm/dd/yyyy):
	b. Institution:
	c. Reason: ☐Recurrent chest pain
7. Was the patient admitted to the hospital (since	Other, specify
index hospitalization/last contact)?	If yes,
	Discharged?
	☐Yes ☐No
	If yes, please provide a copy of the report
	d. Date (mm/dd/yyyy):
	e. Time (hh:mm):
8. Was an ongoing hospitalization prolonged for	☐Yes ☐No
ischemic signs/symptoms?	If yes, please provide a copy of the report

	a. Date of admission:b. Institution:
9. Did the subject have ECG changes (since index hospitalization/last contact)?	☐ Yes ☐ No If Yes, please provide a copy of the ECG If Yes, check appropriate boxes below ☐ ST elevation >1mm ☐ ST depression >1mm ☐ TWI >1mm
10. Were Cardiac biomarkers obtained (since index hospitalization/last contact)? If yes, Peak cTn result?	☐Yes ☐No ☐Yes ☐No Provide peak cTn result: Provide cTn units: Provide cTn ULN:
Peak CK-MB result?	☐Yes ☐No Provide peak CK-MB result: Provide CK-MB units: Provide CK-MB ULN:
11. Was a stress test performed (since index hospitalization/last contact)?	☐Yes ☐No If yes, provide report. If yes, Was it ☐ ETT ☐ Nuclear Imaging If yes, fill out questions about ETT and Nuclear Imaging
12. Was a coronary angiogram performed (since index hospitalization/last contact)?	☐Yes ☐No If yes, fill out questions about the coronary angiogram and provide report.
13. Was a PCI performed (since index hospitalization/last contact)?	☐Yes ☐No If yes, fill out questions about the PCI and provide report.
14. Did subject undergo heart revascularization (since index hospitalization/last contact)?	☐Yes ☐No If yes, fill out questions and provide report. Select method of revascularization: ☐CABG ☐Stent ☐Unknown
15. What source documents have been provided by site?	□ Discharge summary □ Exercise testing report □ Death note, certificate □ Cardiac Cath/PCI report □ CABG report □ Other, specify: □ ECG, during & after event

ADVERSE EVENT FORM

1) AE Number	
2) Event Code	
3) Event Description	

4) Start Date (mm/dd/yyyy):	
5) End Date (mm/dd/yyyy):	☐ Continuing
6) Grade (1-4)	1 - Mild 2 - Moderate 3 - Severe 4 - Life-threatening
7) SAE?	Yes No
8) Was patient withdrawn from study due to AE?	☐ Yes ☐ No
9) Relationship to study procedure	1 - Not related 2 - Unlikely Related 3 - Possibly Related 4 - Probably Related 5 - Definitely Related
10) Relationship to contrast (1-5)	☐ 1 - Not related ☐ 2 - Unlikely Related ☐ 3 - Possibly Related ☐ 4 - Probably Related ☐ 5 - Definitely Related
11) Relationship to underlying disease	☐ 1 - Not related ☐ 2 - Unlikely Related ☐ 3 - Possibly Related ☐ 4 - Probably Related ☐ 5 - Definitely Related
12) Action (1-5)	☐ 1 - No Action Taken ☐ 2 - Medication Given ☐ 3 - Non-drug therapy given ☐ 4 - ED visit ☐ 5 - Hospitalization /prolonged hospitalization
13) Outcome (1-5) 14) Did the subject have another AE?	☐ 1 - Recovered ☐ 2 - Recovered with sequelae ☐ 3 - Ongoing ☐ 4 - Death ☐ 5 - Unknown ☐ Yes ☐ No
14) Did the subject have another AL!	

SERIOUS ADVERSE EVENT FORM

Event Information	
1. Type of Report	☐ Initial Report ☐ 48-72 hour follow up
2. Date of this report (dd/mm/yyyy)	
Contrast Information	
3. Did the subject receive contrast?	☐Yes ☐No
If yes, complete the following:	
Contrast agent:	ml
Dose	ml
4. Time to onset after injection:	
Event Details	
5. Indicate the nature of the diagnosis that best describes the event.	 Myocardial Infarction Bleeding Stroke Renal Failure Anaphylaxis Death Other medically important events Other,
6. Date of onset (dd/mm/yyyy):	
7. Time of onset of event:	
8. Date of outcome (dd/mm/yyyy):	
9. Time of outcome:	
10. Seriousness	□ Death: Date Time: □ Resulted in a life-threatening illness or injury □ Resulted in a permanent impairment of a body structure or function □ Resulted in a hospitalization or prolongation of an existing hospitalization □ Required medical or surgical intervention to prevent permanent impairment or damage □ Congenital anomaly or birth defect in offspring of the subject
11. Was this an unexpected SAE (not listed in the informed consent)	☐Yes ☐No
12. What was the relationship of the SAE to the procedure?	☐ Not related ☐ Possibly related ☐ Probably related ☐ Definitely related ☐ Unable to determine
13. What was the relationship of the SAE to the contrast? 14. What was the relationship of the	 Not related Possibly related Probably related Definitely related Unable to determine Not related
SAE to underlying disease?	Possibly related Probably related Definitely related

	Unable to determine
15. Describe the event:	
16. Describe the action taken:	
17. Outcome:	☐ Resolved: Date (DD/MM/YYYY) ☐ Ongoing ☐ Improved ☐ Unchanged ☐ Worsened ☐ Death - Was an autopsy performed? ☐ Yes ☐ No
18. Attached documentation:	☐ Lab report (s) ☐ ECG (s) ☐ Discharge Summary ☐ Admission History and Physical ☐ Death Certificate ☐ Other
19. Did the subject have another SAE?	Yes No

PROTOCOL DEVIATION FORM

A. Date of protocol deviation: (dd/mm/yyyy)
B. Deviation code: (from list below) C. Reason for Deviation: (i.e. lost to follow-up)
Possible Deviation Codes
1 – CT Group – CT not performed (i.e. subject refusal)
2 – CT Group – (i.e. CT malfunction)
3 – Subject left hospital against medical advice (post-randomization)
4 – 2-3 day follow-up call was done out of window
5 – 28 days follow-up call was done out of window
6 – 1 year follow-up call was done out of window
7 – 2 year follow-up call was done out of window
8 – Biomarker testing issues (i.e. not enough blood, centrifuge broken, sample loss)
9 – Other: (specify)
Did the subject have another Protocol Deviation? Yes No

Note: Protocol Deviations must be reported to Pearl Zakroysky (<u>pzakroysky@partners.org</u>) immediately after deviation occurs. Deviations should also be reported, as required, according to site IRB policy.

PROTOCOL VIOLATION FORM

A. Date of protocol violation: (dd/mm/yyyy)
C. Reason for Violation: (i.e. subject underwent CT with sent in place)
Possible Violation Codes
1 – Subject was randomized but did not meet incl/excl criteria (specify which criteria):
2 – CT Group – CT not performed (i.e. no staff available to perform CT scan)
3 – Failure to sign informed consent
4 – Pregnancy test was not performed in applicable subject
5 – Qualifying labs not performed
6 – Qualifying ECG not performed
7 – Calcium scan not performed
8 – Contrast agent was not given
9 – Coronary CTA – stent was present
10 – 2-3 day follow-up call was not done
11 – 2 year follow-up call was not done
12 – Other: (specify)
Did the subject have another Protocol Violation? Yes No

Note: Protocol Violations must be reported to your IRB, as required, according to site IRB policy. PVs must also be reported to Pearl Zakroysky (<u>pzakroysky@partners.org</u>) immediately after knowledge of the event.