SCREENING FORM

Demographics

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

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" .
Α.	American Indian or Alaskan Native	
Β.	Asian	
С.	White	
D.	Black or African Native	
Ε.	Native Hawaiian or Pacific Islander	
F.	Not reported	

Inclusion/Exclusion Criteria

To be completed on all patients who are screened.

1.		e select yes or no to indicate whether patient		
	meets	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 <a>>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.		e select yes or no to indicate whether patient the following exclusion criteria		
	inversi	New diagnostic ischemic ECG changes ment elevation or depression > 1 mm or T-wave on > 4 mm in two or more anatomically adjacent leads bundle branch block	Yes	🗌 No

2) Documented or self-reported history of CAD MI, percutaneous coronary interventions [PCIs], coronary artery bypass graft [CABG], known significant coronary stenosis [>50%]	🗌 Yes	🗌 No
 Greater than 6 hours since presentation to ED to time of consent 	🗌 Yes	🗌 No
4) BMI >40 kg/m ²	🗌 Yes	🗌 No
 Impaired renal function, as defined by local standard of care, for example, measured serum creatinine >1.5 mg/dL 	🗌 Yes	🗌 No
 Markedly elevated troponin, as defined by local standard of care 	🗌 Yes	🗌 No
 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
10) Documented or self-reported cocaine use within the 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
 Participant with no telephone or cellphone number (preventing follow-up) 	🗌 Yes	🗌 No
 14) Participant with positive pregnancy test within 24 hours prior to CT scan. <u>For woman of childbearing potential</u>, defined as: < 2 years of menopause in the absence of hysterectomy or tubal ligation. 	Yes	🗌 No
 Participant unwilling to provide written informed consent. 	🗌 Yes	🗌 No

ED Evaluation Timeline

1.	Date of ED Presentation (mm/dd/yyyy):	
2.	Time of ED Presentation (hh:mm):	
3.	Date of Initial ED Evaluation	
	(mm/dd/yyyy):	
4.	Time of Completion of Initial ED Evaluation	
	(hh:mm):	
(Th	is is the time point at which the ED	
phy	vsician puts in the 1st set of orders.)	

Randomization & Consent

1. Dat	e of Consent (mm/dd/yyyy):	
2. Tim	e of Consent (hh:mm):	
3. Wa	s the patient randomized?	Yes No*
		Randomization number If no, reason: markedly positive troponin positive pregnancy test patient withdrew consent other, specify
4. Dat	e of Randomization (mm/dd/yyyy):	
5. Tim	e of Randomization (hh:mm):	

MEDICAL HISTORY FORM

Cardiac Risk Factors and Medications

1.	Hypertension	Yes No Not Reported
2.	Diabetes mellitus	None Insulin requiring Non-insulin
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

1. Heart failure Ves No Not Rep

2.	Peripheral vascular disease	🗌 Yes	🗌 No	Not Reported
3.	Chronic lung disease/COPD	🗌 Yes	🗌 No	Not Reported
4.	Cerebrovascular event (stroke)	🗌 Yes	🗌 No	Not Reported

Pain Characteristics/Symptoms

Patient reported data:

	Anginal Chest Pain or equivalent
	Epigastric Pain
1. Chief Complaint	Arm/Jaw/Shoulder Pain
	Shortness of Breath
	Other:
	Date (mm/dd/yyyy)
2. Most recent Episode	Time (hh:mm)
	Duration (minutes):

ED VISIT FORM

Initial ED Vital Signs

Data collected by CRC from ED chart.

1. Weight:	lbs		
2. Height:	inches		
3. Resting heart rate:	bpm		
4. Systolic BP:	mmHg		
5. Diastolic BP:	mmHg		
6. Presence of rales?	Yes No Not Reported		

ED Medications

Data collected from ED record. Select ALL that apply.

1.	Aspirin	
2.	Nitrates	
3.	Beta blocker	
4.	Morphine	
5.	Heparin/ Low molecular weight	
	heparin/ Fragmin/ Lovenox	
6.	Plavix	

Laboratory Results

Data collected from ED record.

Test	Date	Time	Result	Not done
Creatinine (initial)			mg/dL	

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	

Troponin Values

Test	Troponin classification	Date	Time	Result	Range	Not done
Troponi n (initial)	T			ug/ml	Normal Enter Range: Borderline Enter Range: Elevated Enter Range:	
Troponi n (2 nd)	T [] I []			ug/ml	Normal Enter Range: Borderline Enter Range: Elevated Enter Range:	
Troponi n (3 rd)	T [] I []			ug/ml	Normal Enter Range: Borderline Enter Range: Elevated Enter Range:	

Biomarker Testing

Did the patient consent to biomarker testing? Yes No
If yes,
Draw #1: Was blood collected and stored? If 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?
now many daughter tubes:
Green tube specimen ID no
How many daughter tubes?
Draw #2: Was blood collected and stored? If 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?
now many daughter tubes:
Green tube specimen ID no
How many daughter tubes?
Draw #3: Was blood collected and stored? If less than 3 tubes collected, fill out protocol deviation form.
\square Yes \square No
Date (mm/dd/yyyy):
Time (hh:mm):
Red tube specimen ID no
How many daughter tubes?
now many daughter tubes:
Purple tube specimen ID no
How many daughter tubes?
How many daughter tubes?
Crean tube encommon ID no
Green tube specimen ID no How many daughter tubes?
now many daughter tubes:

ECG FORM

Initial 12-Lead ECG Interpretation

Information entered into eCRF by CRC.

1. 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.

1. Was CCTA performed	Yes No
	If no, indicate why not done:
For interventional arm: If not performed,	Definite ACS (positive troponin, ECG changes)
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
	Philips
	Other
	Model: Somatom Sensation 64
	Lightspeed 64
	Lightspeed VCT
	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	
If no, give reason and fill out protocol	Yes No
violation form	
3. CTA	Yes No
4. Intra CCTA vitals:	have
Average HR during scan:	bpm
5. Pre-procedure medications:	
	Yes No
a. Beta blocker IV	If yes, 🔄 Metoprolol
	Other
	dose: mg
	Yes No
b. Beta blocker PO	
	Atenolol
	dose:mg
c. Nitroglycerin SL	Yes No
	If yes, dose:

	Isovue	
	Omnipaque	
6. Contrast agent:		
	Other	
	Specify:	
	300	
a. concentration mg iodine	320	
per ml	350	
	370	
	Yes No	
	If no, indicate why not done:	
	_	
7. Completion of the CT scan	Medical reason	
7. completion of the of seam	Patient refusal/withdrawal	
	Equipment failure	
	Other	
	If other, specify:	
9 Decementionales etc. 1/4-is some discution (7)	Yes No	
8. Prospectively gated/triggered cardiac CT		
9 . Retrospectively gated cardiac CTA scan	🗌 Yes 🗌 No	
10. Dose Length Product of CTA only:	mGY cm	
11. Total Dose Length Product	mGY cm	
12. CTDI Volume of CTA	mGy	

CT Test Subject Physician Reading Form To be completed by CT reader with signature next to physician ID on paper CRF; information entered on form by CRC.

1. Reading physician ID: (Please have CT Reader initial paper CRF)	
2. Calcium Score	
3. Coronary CTA	
Fill out the appropriate box to indicate the level of	of stenosis. If level of stenosis equals stent, please fill
out the protocol violation form.	
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 or
	minor) 50-69% (moderate)
	70-99% (significant/severe) 100% (occluded)
	indeterminate stent**
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 Abnormal Normal Global LV function in % Regional Wall Motion Abnormality: Yes No If yes, match stenosis territory Anterior/apex Inferior/posterior Lateral	
6. If retrospectively gated, was tube modulation technique or a similar radiation safety technique used?	☐ Yes ☐ No	
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 	
	ecord (MR). If evidence of a stent is documented in	
the MR, fill out the protocol violation form.		

DIAGNOSTIC TESTING FORM

Nuclear Imaging

1.	Was nuclear imaging done?	Yes No
2.	What are the initials of the	
	physician who reported it?	
2	Date/time test ordered:	Date (mm/dd/yyyy):
5. Date/ time test of defed	Dates time test of defed.	Time (hh:mm):
4	4. Date/time test was performed:	Date (mm/dd/yyyy):
4.		Time (hh:mm):
Б	Date/time of test interpretation:	Date (mm/dd/yyyy):
5. Date/time of test interpret	Date/ time of test interpretation.	Time (hh:mm):
		Rest Stress Rest & Stress
		If stress, select one of the following:
6.	Modality:	ETT (go to qs.7)
		Pharmacologic (go to qs. 9)

7.	Bruce	
	Modified Bruce Time to end of exercise	
If ETT,	Naughtonminsec	
	Supine Bicycle METS	
	Upright Bicycle %MPHR	
8. ECG changes meeting criteria for	Yes No	
ischemia?	If yes, specify changes:	
	o ST depression Yes No	
	If yes, what is the maximum depression?mm	
	◦ ST elevation Yes No	
	If yes, what is the maximum elevation?mm	
	• Ventricular arrhythmias Yes No	16
	o Other ∐Yes ∐No, if yes, spec	lfy
10. If pharmacological, list the agent		
used:		
11. Rest protocol tracer:		
•	Technetium	
	Tetrafosmin	
administered activity /unit of	Thallium	
activity	(Mega Bq/millicuries)	
12. Stress Protocol tracer		
	E Technetium	
	Tetrafosmin	
administered activity /unit of	Thallium	
activity	(Mega Bq/millicuries)	
13. Was a Reinjection performed?		
	Yes No	
	If yes, fill out the following:	
administered activity /unit of	│	
activity	(Mega Bq/millicuries)	
14. Was a Rubidium test performed?	If yes,	
rest	administered activity /unit of activity(Mega	
stress	Bq/millicuries)	
	administered activity /unit of activity(Mega	
	Bq/millicuries)	
	Not done Done and completed Performed but not	
	completed	
15. Completion of Protocol	Baseline Heart rate bpm	
	Peak Heart Rate bpm	
	Systolic Blood Pressure at rest mmHg	
	Diastolic Blood Pressure at restmmHg	
	Systolic Blood Pressure at peak stress mmHg	
	Diastolic Blood Pressure at peak stressmmHg	

	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 Yes No If yes, did the chest pain limit exercising capacity? Yes No Shortness of Breath Yes No Hypotension Yes No VT or non sustained VT Yes No Patient request Yes No Abnormal BP response Yes No Other Yes No If yes, specify: Specify: Specify:
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
 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 Time to end of exercise Modified Bruce Time to end of exercise Naughton minsec Supine Bicycle METS Upright Bicycle %MPHR
8. If Dobutamine:	Maximum dobutamine dose given:- mcg/kg/min Atropine given?: Yes No If yes, dose:mg Handgrip use?: Yes No %MPHR Biphasic response Yes No
9. ECG changes:	Yes No If yes, specify changes: ST depression 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 Yes No Other Yes
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

☐ 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 Yes No If yes, did the chest pain limit exercising capacity? Yes No Shortness of Breath Yes No Hypotension Yes No VT Yes No Patient request Yes No Abnormal BP response Yes No Other Yes No If yes, specify: Specify: Specify:
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 infero- posterior segment normal on stress?	□Yes □No
15. Resting LVEF	EF%
16. Stress LVEF	EF% Normal Abnormal If abnormal, severely decreased (<35% EF) Yes No
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

19. Was another	Stress Echocardiogram
done?	

Yes No

Transthoracic Echocardiogram (rest)

To be entered on form by CRC

1. Was a resting transthoracic echocardiogram 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. 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.

1. 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):
3. Date/time test ordered:	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 □ Regadenoson Symptoms of possible CAD (including CP, SOB) □Yes No □equivocal (If the answer is yes or equivocal, go to qs. 9)
9. If there were symptoms of possible CAD, enlist any other symptoms perceived by the patient.	Chest Pain Yes No If yes, did the chest pain limit exercising capacity? Yes Yes No If yes,Ischemic Equivocal Shortness of Breath Yes No Hypotension Yes No VT or non sustained VT Yes No Patient request Yes No Abnormal BP response Yes No Other Yes No If yes, specify: Yes No
10. Results:	□Negative □Positive □Borderline If positive or borderline, select as appropriate: □ □ST depression □Yes □No If yes, what was the maximum? □ST elevation □Yes □No If yes, what was the maximum? □ST elevation □Yes □No □If yes, what was the maximum? □Ventricular arrhythmias □Yes □No □Other □Yes □No If yes, specify:
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):
	Date (mm/dd/yyyy):
5. Date/time of test interpretation:	Time (hh:mm):
6. Were there any complications to the	Yes No
procedure (as per cath lab ACC/NCDR	
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)
	\Box 70-99% (significant/severe) \Box 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)	\Box normal 0% \Box 1-49% (non-significant/mild
	or minor) 50-69% (moderate)
	(occluded) indeterminate stent
	note:
e. LV Gram	Normal Abnormal
8. Did subject undergo revascularization?	Yes No
	If yes, type of revascularization:
	LCX Yes No
9. Radiation Exposure	Fluoro time Min/sec
-	Cine runs Number
	Radiation Dose
10. Cardiac Catheterization done again?	Yes No

PATIENT DISCHARGE FORM Patient Discharge Information

	Direct ED Discharge
	Observational Unit admission
	Hospital admission
	Died prior to ED discharge; (If so, fill out
	SAE form)
1. Disposition:	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 Data /time of index beenital disabarge	Date (mm/dd/yyyy):
2. Date/time of index hospital discharge:	Time (hh:mm):
	Yes No
3. Was the subject admitted to the hospital?	Medical/surgical unit
If so where?	Step down unit
	Noncardiac chest pain
	Non coronary cardiac chest pain
4. Primary discharge diagnosis (Choose One):	Acute Coronary Syndrome
	Cardiac chest pain not meeting Acute
	Coronary Syndrome
	Pulmonary embolism
	Pneumonia
	GERD
	Gastrointestinal
5. If Non cardiac Chest Pain, (Choose one):	Musculoskeletal
	Aortic dissection
	Non cardiac CP without clear alternate
	diagnosis
	Other, specify
	Pericarditis/Myocarditis
6. If, Non coronary cardiac chest pain, (Choose	
One):	
	Cardiomyopathy
	Other
	Myocardial Infarction (defined as 1 and 2)
	1. Anginal equivalent > 10 minutes AND
	Typical rise and fall of cardiac
	biomarkers
7. If Acute Coronary Syndrome, (Choose One):	(record peak cTn or peak CK-MB)
	(Provide Units and ULN:)
	Upstable Angine (defined as 1 and 2)
	Unstable Angina (defined as 1 and 2)
	1. Chest pain or anginal equivalent at

	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
· ·	Anaphylaxis 🗌 Yes 🗌 No

48-72 HOUR FOLLOW UP FORM

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

1. Was the 48-72 hour follow-up call completed?	Yes 🗌 No 🗌 NA
	If No, Did the subject withdraw from the study? 🗌 Yes 🗌 No
	If yes, reason:
2. 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
5. Did subject die?* If yes, fill out SAE form.	Yes No If yes, death reported how? Relative SSDI Medical record
a. Date of death (mm/dd/yyyy):	
b. Time of death (hh:mm):	
c. Cause of death:	 CV death due to coronary heart disease 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?	Yes No If yes, complete supplement form
8. Did subject return to OPD (since index	
hospitalization/last contact)?	If yes, complete supplement form
9. Was the patient admitted to the hospital?	Yes No If yes, complete supplement form
10. Was an ongoing hospitalization prolonged for ischemic signs/symptoms?	Yes No If yes, complete supplement form
11. Did subject have ECG changes (since index	
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?	
*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 Cardiology consultation note CABG report Biomarker report Other, specify ECG, during & after event Other, specify

48-72 HOUR FOLLOW UP SUPPLEMENT FORM

	Was the 48-72 hour follow-up call completed?	□ Yes □ No □ NA
1.		If No, Did the subject withdraw from the study? Yes No
		If yes, reason:
2.	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
5.	Did subject die?* If yes, fill out SAE form.	Yes No If yes, death reported how? Relative SSDI Medical record
	a. Date of death (mm/dd/yyyy):	
	b. Time of death (hh:mm):	
	c. Cause of death:	CV death due to coronary heart disease 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?	Yes No If yes, 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	
	Discharged?	
	Yes No	
	If yes,	
	e. Date (mm/dd/yyyy):	
	f. Time (hh:mm):	
	If yes,	
	-	
	a. Date of return (mm/dd/yyyy):	
	b. Time of return (hh:mm):	
	c. Institution:	
	d. Reason:	
	Recurrent chest pain*	
8. Did subject return to OPD (since index	Other, specify	
hospitalization/last contact)?	*Fill out SAE form	
	If yes,	
	Discharged?	
	Yes No	
	If yes,	
	e. Date (mm/dd/yyyy):	
	f. Time (hh:mm):	
	— —	
	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	
	*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):	
	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	AE TYes * 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.		
	If yes, you will need to fill out the PCI questions and	
	provide report.	
	If yes, provide report.	
16. Did subject undergo heart revascularization?	If yes, select method of revascularization:	
*If yes, fill out SAE form		
The yes, the out sale torth	Stent	
	Stroke Yes No	
17. Did the subject have any peri-procedural		
complications? * If yes, fill out SAE form	Renal failure Yes No	
	Anaphylaxis Yes No	
	Discharge summary	
18. What source documents have been provided by	Death note, certificate Cardiac Cath/PCI report	
site?	Cardiology consultation note	
51(0)	Biomarker report Other, specify	
	ECG, during & after event	

28 DAY FOLLOW UP 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 hospitalization/last contact)?	Yes No If yes, death reported how? Relative SSDI Medical record If yes, provide death note, certificate.
d. Date of death:	

a Time of death (hhymm):	
e. Time of death (hh:mm):	CV death due to coronamy heart disease
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	Yes No
anginal equivalent (since index hospitalization/last contact)?	If yes, provide, duration of longest episode:
5. Did subject return to ED (since index	Yes No
hospitalization/last contact)?	If yes, complete supplement form and provide report
6. Did subject return to OPD (since index	Yes No
hospitalization/last contact)?	If yes, complete supplement form and provide report
7. Was the patient admitted to the hospital (since	Yes No
index hospitalization/last contact)?	If yes, complete supplement form and provide report
8. Was an ongoing hospitalization prolonged for	Yes No
ischemic signs/symptoms?	If yes, complete supplement form and provide report
9. Did the subject have ECG changes (since index	Yes No
hospitalization/last contact)?	If Yes, complete supplement form and provide a copy of the
	ECG
10. Were Cardiac biomarkers obtained (since	Yes No
index hospitalization/last contact)?	If yes, complete supplement form
11. Was a stress test performed (since index	□Yes □No
hospitalization/last contact)?	If yes, complete supplement form and provide report
12. Was a coronary angiogram performed (since	Yes No
index hospitalization/last contact)?	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	□Yes □No
(since index hospitalization/last contact)?	If yes, complete supplement form and provide report
15. What source documents have been provided by site?	Discharge summary Exercise testing report Death note, certificate Cardiac Cath/PCI report Cardiology consultation note CABG report Biomarker 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
	hospitalization/last contact)?	If yes, death reported how?

	Relative	
	Medical record	
	If yes, provide death note, certificate.	
g. Date of death:		
h. Time of death (hh:mm):		
	CV death due to coronary heart disease	
i. Cause of death:	CV death not directly due to coronary heart disease	
	Non CV death	
	U Other	
4. Did subject have recurrence of chest pain or	Yes No	
anginal equivalent (since index	If was any side downling of law post online de	
hospitalization/last contact)?	If yes, provide, duration of longest episode:	
	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:	
	Other, specify	
	*Please provide a copy of the report	
	Yes No	
	If yes,	
	a. Date of admission (mm/dd/yyyy):	
	b. Institution:	
	c. Reason:	
7. Was the patient admitted to the hospital (since	Recurrent chest pain	
index hospitalization/last contact)?	Other, specify	
	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		
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	Yes No	
	— —	
hospitalization/last contact)?	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	
Peak chillesuit?	— —	
	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)?	If yes, provide report.	
	If yes,	
	Was it ETT Nuclear Imaging	
	0 0	
10	If yes, fill out questions about ETT and Nuclear Imaging	
12. Was a coronary angiogram performed (since	Yes No	
index hospitalization/last contact)?	If yes, fill out questions about the coronary angiogram and	
	provide report.	
13. Was a PCI performed (since index	TYes No	
hospitalization/last contact)?	If yes, fill out questions about the PCI and provide report.	
	Yes No	
14 Did authiast underne beaut revease derivation	If yes, fill out questions and provide report.	
14. Did subject undergo heart revascularization	Select method of revascularization:	
(since index hospitalization/last contact)?		
	Stent	
15. What source documents have been provided	Death note, certificate Cardiac Cath/PCI report	
by site?	Cardiology consultation note	
	Biomarker 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)	 1 - Recovered 2 - Recovered with sequelae 3 - Ongoing 4 - Death 5 - Unknown
14) Did the subject have another AE?	Ves 🗌 No

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	Myocardial Infarction
that best describes the event.	
	Renal Failure
	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:	
	Death : Date Time :
10. Seriousness	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
11 Was this on unarrested SAE (not	the subject
11. Was this an unexpected SAE (not listed in the informed consent)	
12. What was the relationship of the	Not related
SAE to the procedure?	Possibly related
SAL to the procedure.	Probably related
	Definitely related
	Unable to determine
13. What was the relationship of the	
SAE to the contrast?	Possibly related Probably related
	Definitely related
	Unable to determine
14. What was the relationship of the	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?

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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

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A. Date of protocol violation: (dd/mm/yyyy)
 B. Violation code: (from list below) 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?

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.