AIM-HIGH

ACS EVENT

SITE ID: _____ _____ PATIENT ID: ___ ___ ___

Patient Initials: ___ ___ ___ ____

INSTRUCTIONS: Fill this form out if the patient is admitted for evaluation/treatment of any possible ACS event (MI, ACS, etc)

Table Name: ACS

BE SURE TO SUBMIT ALL DOCUMENTING MATERIALS TO AXIO RESEARCH AS SOON AS POSSIBLE.

1.	Date of onset of symptoms *(mm/dd/yyyy)* ACS_OnsetDt	___ ___ / ___ ___ / ___ ___ ___ ___ USE (MM / DD / YYYY)
2.	Date of admission *(mm/dd/yyyy)* ACS_adminDt	___ ___ / ___ ___ / ___ ___ ___ ___ USE (MM / DD / YYYY)
3.	Date of discharge *(mm/dd/yyyy)* ACS_discDt	___ ___ / ___ ___ / ___ ___ ___ ___ USE (MM / DD / YYYY)
4.	Which of the following did the patient experience? ACS_event	☐ 1 MI ☐ 2 UNSTABLE ANGINA ☐ 3 NO DOCUMENTED ISCHEMIA
5.	Did patient experience angina or angina equivalent symptoms within 24 hours prior to event? ACS_angina	☐ 0 NO ☐ 1 YES
6.	If yes, what was the duration of symptoms? ACS_AnginaDuration	☐ 1 <1HR BUT > 5 MIN ☐ 3 24-48 HOURS ☐ 2 1-24 HOURS ☐ 4 >48 HOURS
7.	Were cardiac enzyme measurements taken? If yes, add values to the Enzyme log form ACS_enzyme	☐ 0 NO ☐ 1 YES
8.	Were ECGs obtained? ACS_ECG If yes, please fill out an ECG form for each	☐ 0 NO ☐ 1 YES
9.	Did patient undergo PCI within 24 hours or CABG within 72 hours of the onset of symptoms? ACS_RevascPreACS	☐ 1 NO ☐ 2 PCI ☐ 3 CABG
10.	Was revascularization procedure performed **FOLLOWING** the event? If yes, please fill out Revascularization form. ACS_RevascPostACS	☐ 1 NO ☐ 2 PCI ☐ 3 CABG
11.	Did the patient die within 30 days of this event? If yes, please complete Death form. ACS_Fatal	☐ 0 NO ☐ 1 YES

AIM-HIGH

ADVERSE EVENT

SITE ID: _____ _____ PATIENT ID: ___ ___ ___

Patient Initials: ___ ___ ___ ____

Instructions: Please complete for any adverse event

Table Name: AE

(Do NOT fill out this page if AE was diagnosed as MI, other coronary event, stroke, or other CNS event please fill out the corresponding Cardiac Event or CNS Event page)

1.	Start Date *(mm/dd/yyyy)* AE_StDate	___ ___ / ___ ___ / ___ ___ ___ ___ Use (MM / DD / YYYY)
2.	Is the condition continuing? AE_Continu	☐ 0 NO ☐ 1 YES
3.	If no, End Date *(mm/dd/yyyy)* AE_EndDate	___ ___ / ___ ___ / ___ ___ ___ ___ Use (MM / DD / YYYY)
4.	Give a description of the adverse event AE_Text	_____ _____ _____ _____ _____
5.	Was the event/condition serious? AE_Serious	☐ 0 NO ☐ 1 YES

An Event is Serious if it meets any of the criteria below

Results in death, is life-threatening, requires in-patient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, is a congenital anomaly/birth defect and/or is a medically important event.

If the event is serious, complete the SAE form within 24 hours of learning of the event.

6.	Severity AE_Severit	☐ 0 NO SYMPTOMS ☐ 2 MODERATE ☐ 1 MILD ☐ 3 SEVERE
7.	Did the event/condition require treatment? AE_Treat	☐ 0 NO TREATMENT REQUIRED ☐ 1 DRUG TREATMENT ☐ 3 BOTH DRUGS AND SURGERY ☐ 2 SURGICAL TREATMENT ☐ 4 OTHER
8.	Sequelae AE_Outcome If yes for Death, fill out Death from.	☐ 1 RECOVERED, NO SEQUELAE ☐ 3 NOT RECOVERED ☐ 2 RECOVERED WITH SEQUELAE ☐ 4 DEATH
9.	Was the event/condition related to or caused by the study drug? AE_Cause1	☐ 1 DEFINITELY NOT RELATED ☐ 3 POSSIBLY RELATED ☐ 2 PROBABLY NOT RELATED ☐ 4 RELATED
10.	Did the event/condition result in any changes to the use of the study drug? If yes, fill out Dose Adjustment form. AE_Drug	☐ 0 NO CHANGES MADE ☐ 2 STUDY DRUG(S) DOSE DECREASED ☐ 1 STUDY DRUG(S) USE INTERRUPTED ☐ 3 STUDY DRUG(S) DISCONTINUED

AIM-HIGH

SITE ID: _____ _____ PATIENT ID: ___ ___ ___

Patient Initials: ___ ___ ___ ____

Amendment 6 Follow-up

Table Name: AFUP

INSTRUCTIONS: Please complete at the Amendment 6 Follow-up visit.

	Visit	☐ INTERIM VISIT ☐ FINAL VISIT
1.	Type of visit	☐ 1 PHONE CALL ☐ 2 IN-OFFICE ☐ 3 VISIT NOT DONE AFUP_VisitTp
2.	Date of visit or phone call (MM/DD/YYYY)	___ ___/ ___ ___/ ___ ___ ___ ___ AFUP_VisitDt
3.	If visit was not done, please indicate why:	☐ 1 PARTICIPANT DIED PRIOR TO FOLLOW-UP. **(If not already completed, please complete Death CRF and submit documenting materials)** ☐ 2 PARTICIPANT DECLINED FURTHER PARTICIPATION PRIOR TO THIS VISIT ☐ 3 UNABLE TO CONTACT PARTICIPANT AFTER AT LEAST 5 DIFFERENT ATTEMPTS (PLEASE CONTACT COORDINATING CENTER FOR GUIDANCE) AFUP_VisitNtDn

Query the participants carefully about the following possible events:

4.	**MI**: Did the participant have an MI? (If yes, complete ACS Event CRF and submit documenting materials)	☐ 0 NO	☐ 1 YES AFUP_MI
5.	**ACS**: Was the participant hospitalized for >23 hours for confirmed chest pain/angina/acute coronary syndrome? (If yes, complete ACS Event CRF and submit documenting materials)	☐ 0 NO	☐ 1 YES AFUP_ACS
6.	**Cardiac Revascularization**: Did the participant have a revascularization of the coronary arteries (CABG or PCI)? (If yes, complete Revascularization CRF and submit documenting materials.)	☐ 0 NO	☐ 1 YES AFUP_CardRevas
7.	**Cerebrovascular Revascularization:** Did the participant have a revascularization of the carotid arteries (carotid endarterectomy, carotid PTA)? (If yes, complete Revascularization CRF and submit documenting materials)	☐ 0 NO	☐ 1 YES AFUP_CerebRevas
8.	**Peripheral Revascularization**: Did the participant have a revascularization of peripheral arteries (fem-pop bypass or femoral angioplasty)? (If yes, complete Revascularization CRF and submit documenting materials)	☐ 0 NO	☐ 1 YES AFUP_PeriRevas
9.	**Stroke/TIA**: Did the participant have a neurological event that fits the definition of a possible TIA or stroke? (If yes, complete CNS Event CRF and submit documenting materials)	☐ 0 NO	☐ 1 YES AFUP_StrokeTIA

SIGNATURE_____ DATE_____

AIM-HIGH

SITE ID: _____ _____ PATIENT ID: ___ ___ ___

Patient Initials: ___ ___ ___ ____

Table Name: LI

Current Lipid Therapies

INSTRUCTIONS: Please complete this form noting all lipid medications the participant is routinely taking at the time of this visit.

	Visit	☐ INTERIM VISIT	☐ FINAL VISIT
	Statins		
1.	Atorvastatin (Lipitor) LI_Ator	☐0 NO	☐1 YES
2.	Dose per day in **mg**: LI_AtorDose	_____	
3.	Fluvastatin (Lescol) LI_Fluv	☐0 NO	☐1 YES
4.	Dose per day in **mg**: LI_FluvDose	_____	
5.	Lovastatin (Mevacor, Altopre, Altocor) LI_Lova	☐0 NO	☐1 YES
6.	Dose per day in **mg**: LI_LovaDose	_____	
7.	Pravastatin (Pravachchol) LI_Prava	☐0 NO	☐1 YES
8.	Dose per day in **mg**: LI_PravaDose	_____	
9.	Rosuvastatin (Crestor) LI_Rosu	☐0 NO	☐1 YES
10.	Dose per day in **mg**: LI_RosuDose	_____	
11.	Simvastatin (Zocor) LI_Simv	☐0 NO	☐1 YES
12.	Dose per day in **mg**: LI_SimvDose	_____	
13.	Other statin LI_OthSta	☐0 NO	☐1 YES
14.	Please specify: LI_SpcSta	_____	
15.	Dose per day in **mg**: LI_OthStaDose	_____	
	Combination Medications		
For the combination medication, please enter the dose in this format (xx/xx)			
16.	Lovastatin + niacin (Advicor) LI_Advi	☐0 NO	☐1 YES
17.	Dose per day in **mg**: LI_AdviDose	_____	
18.	Atorvastatin + amlodipine (Caduet) LI_Cadu	☐0 NO	☐1 YES
19.	Dose per day in **mg**: LI_CaduDose	_____	
20.	Simvastatin +ezetimibe (Vytorin) LI_Vyto	☐0 NO	☐1 YES
21.	Dose per day in **mg**: LI_VytoDose	_____	
22.	Pravastatin + aspirin (Pravigard Pac) LI_Pravi	☐0 NO	☐1 YES
23.	Dose per day in **mg**: LI_PraviDose	_____	
24.	Simvastatin + niacin (Simcor) LI_Simc	☐0 NO	☐1 YES
25.	Dose per day in **mg**: LI_SimcDose	_____	
26.	Other combination medication: LI_OthCom	☐0 NO	☐1 YES

SIGNATURE_____ DATE_____

27.	Please specify: LI_SpcCom	_____
28.	Dose per day in **mg**: LI_OthComDose	_____
	Fibrates	
29.	Gemfibrozil (Lopid) LI_Gemf	☐ 0 NO ☐ 1 YES
30.	Dose per day in **mg**: LI_GemfDose	_____
31.	Fenofibrate (Antara, Lofibra, Tricor or Triglide) LI_Feno	☐ 0 NO ☐ 1 YES
32.	Dose per day in **mg**: LI_FenoDose	_____
33.	Fenofibric acid (Trilipix, Fibricor) LI_FenoAcid	☐ 0 NO ☐ 1 YES
34.	Dose per day in **mg**: LI_FenoAcidDose	_____
35.	Clofibrate (Atromid-S) LI_Clof	☐ 0 NO ☐ 1 YES
36.	Dose per day in **mg**: LI_ClofDose	_____
37.	Other fibrate: LI_OthFib	☐ 0 NO ☐ 1 YES
38.	Please specify: LI_SpcFib	_____
39.	Dose per day in **mg**: LI_OthFibDose	_____
	Niacins	
40.	Niaspan LI_Niaspan	☐ 0 NO ☐ 1 YES
41.	Dose per day in **mg**: LI_NiaspanDose	_____
42.	Slo-Niacin LI_SloNia	☐ 0 NO ☐ 1 YES
43.	Dose per day in **mg**: LI_SloNiaDose	_____
44.	Niacin SR LI_SRNia	☐ 0 NO ☐ 1 YES
45.	Dose per day in **mg**: LI_SRNiaDose	_____
46.	Niacin IR LI_IRNia	☐ 0 NO ☐ 1 YES
47.	Dose per day in **mg**: LI_IRNiaDose	_____
	Resins (bile acid sequestrants)	
48.	Cholestyramine (Questran, Questran Light, Prevalite, Locholest, Locholest Light) LI_Cholesty	☐ 0 NO ☐ 1 YES
49.	Dose per day in **gram**: LI_CholestyDose	_____
50.	Colestipol (Cholestid) LI_Colesti	☐ 0 NO ☐ 1 YES
51.	Dose per day in **gram**: LI_ColestiDose	_____
52.	Colesevelam HCL (WelChol) LI_Colesev	☐ 0 NO ☐ 1 YES
53.	Dose per day in **mg**: LI_ColesevDose	_____
54.	Other resins: LI_OthRes	☐ 0 NO ☐ 1 YES
55.	Please specify: LI_SpcRes	_____

SIGNATURE_____ DATE_____

56.	Dose per day in **mg**: LI_OthResDose	_____
	Selective Cholesterol absorption inhibitors	
57.	Ezetimibe (Zetia) LI_Ezeti	☐ 0 NO ☐ 1 YES
58.	Dose per day in **mg**: LI_EzetiDose	_____
	Ask the participant if they are participating in another clinical trial involving lipid modifying therapies.	
59.	Are they participating in a clinical trial of **lipid modifying** therapy? LI_Trial	☐ 0 NO ☐ 1 YES
	If yes, please indicate the name of the trial, the agent being tested and the total daily dose of the investigational product (realizing that it may be the active drug or placebo).	
60.	Investigational drug: anacetrapib, - Clinical Trial – "DEFINE" LI_Define	☐ 0 NO ☐ 1 YES
61.	Dose per day in **mg**: LI_DefineDose	_____
62.	Investigational drug; dalcetrapib – Clinical Trial –"Dal-ACUTE" LI_Acute	☐ 0 NO ☐ 1 YES
63.	Dose per day in **mg**: LI_AcuteDose	_____
64.	Other lipid modifying therapy trial? LI_OthTrial	☐ 0 NO ☐ 1 YES
65.	If so, what is the name of the trial? LI_TrialName	_____
66.	Name of investigational product: LI_TrialProd	_____
67.	Dose per day in **mg**: LI_TrialDose	_____

SIGNATURE_____ DATE_____

SITE ID: _____ _____ PATIENT ID: ___ ___ ___

Patient Initials: ___ ___ ___ ____

Table Name: SSQ

Stroke Symptoms Questionnaire

INSTRUCTIONS: Please complete at the Amendment 6 Follow-up visit.

1.	Date of contact (MM/DD/YYYY)	SSQ_VisitDt ___ ___/ ___ ___/ ___ ___ ___ ___
2.	Has the patient had any sudden loss in the ability to speak clearly for no obvious reason?	☐ 0 NO ☐ 1 YES SSQ_Speak
3.	Has the patient had any sudden paralysis or weakness of an arm, leg or one side of the body?	☐ 0 NO ☐ 1 YES SSQ_Paralysis
4.	Has the patient experienced any sudden dizziness, sensation of spinning, loss of balance or sudden veering or lurching to one side while walking?	☐ 0 NO ☐ 1 YES SSQ_Dizzy
5.	Has the patient had any numbness, tingling or a dead feeling of an arm, leg or down one side of the body (not due to leaning on or keeping the arm or leg in a certain position)?	☐ 0 NO ☐ 1 YES SSQ_Numb
6.	Has the patient had any sudden loss of vision in one or both eyes, loss of the ability to see things to one side, or double vision?	☐ 0 NO ☐ 1 YES SSQ_Vision

If **YES** to any of the above, please have the patient sign a medical release of information form and request the medical records from the patient's personal physician to determine whether there has been a possible ischemic neurological event (stroke or TIA). Complete the CNS Event form and submit documenting materials to the Elaine Nasco at Axio.

If **YES** to any of the above, but their physician has NOT diagnosed a stroke or TIA, please encourage the patient to discuss these symptoms with their PCP. Notify your PI about the patient's symptoms. Your PI may want to call the patient's PCP to discuss whether a neurological work-up is warranted. The need for a neurological work-up may depend on the nature of the patient's symptoms, concomitant illnesses and medications. It should be explained to the patient that it is their responsibility to pursue further diagnosis and treatment. Call the patient to ascertain they have followed-up with their PCP and request records for event documentation as needed. Complete the CNS Event form and submit documenting materials to Elaine Nasco at Axio.

SIGNATURE_____ DATE_____

AIM-HIGH

BASELINE

SITE ID: _____ _____ PATIENT ID: ___ ___ ___

Patient Initials: ___ ___ ___ ____

INSTRUCTIONS: Please complete at the Baseline visit (the start of the Run-In Phase).

Table Name: BL

1.	Visit Date *(mm/dd/yyyy)*	BL_VisDt ___ ___ / ___ ___ / ___ ___ ___ ___ Use (MM / DD / YYYY)
2.	Date of baseline blood draw *(mm/dd/yyyy)*	BL_BldDate ___ ___ / ___ ___ / ___ ___ ___ ___ Use (MM / DD / YYYY)
3.	Was blood drawn in a fasting state?	☐ 0 NO ☐ 1 YES BL_Fasting
4-5.	Screening LDL	___ ___ ___ BL_LDL ☐ 1 MG/DL ☐ 2 MMOL/L BL_LDLUnit
6-7.	Screening HDL	___ ___ ___ BL_HDL ☐ 1 MG/DL ☐ 2 MMOL/L BL_HDLUnit
8-9.	Screening Triglyceride	___ ___ ___ BL_Tg ☐ 1 MG/DL ☐ 2 MMOL/L BL_TgUnit
10.	Was patient taking statins prior to screening?	☐ 0 NO ☐ 1 YES BL_LipidOnStatin
11.	Has patient ever taken niacin or Niaspan?	☐ 0 NO ☐ 1 YES BL_PriorNiacin
Indicate which lipid modifying treatments (if any) the patient has taken within the <u>past month</u>		
12.	Statins	☐ 0 NO ☐ 1 YES BL_Statin
13.	Bile Acid sequestrates	☐ 0 NO ☐ 1 YES BL_BileAcid
14.	Nicotinic acid other than niacin/niaspan	☐ 0 NO ☐ 1 YES BL_Nicotin
15.	Fibric acids	☐ 0 NO ☐ 1 YES BL_Fibric
16.	Cholesterol absorption inhibitors	☐ 0 NO ☐ 1 YES BL_Absorb
17.	Other lipid modifying agents	☐ 0 NO ☐ 1 YES BL_OtherDr
18.	Therapeutic lifestyle changes (diet & exercise) ONLY	☐ 0 NO ☐ 1 YES BL_TLC
19.	Was patient counseled at this visit regarding diet/exercise for lipid control?	☐ 0 NO ☐ 1 YES BL_counsel

AIM-HIGH

BLOOD DRAW/ LDL FOLLOW-UP

SITE ID: _____ _____ PATIENT ID: ___ ___ ___

Patient Initials: ___ ___ ___ ____

Table Name: FLab

INSTRUCTIONS: Fill this form at each visit that requires a blood draw.

	Visit INCL_Age	☐ 1 MONTH	☐ 3 MONTHS	☐ 6 MONTHS
		☐ 12 MONTHS	☐ 24 MONTHS	☐ 36 MONTHS
		☐ 48 MONTHS	☐ END OF STUDY	IF OTHER VISIT, ___ ___ MONTH
1.	Date of lipid & serum chemistry sample collection FLab_LipidDt	___ ___ / ___ ___ / ___ ___ ___ ___ USE (MM / DD / YYYY)		
2.	Was blood drawn for lipids and serum chemistries in a fasting state? FLab_Fast	☐ 0 NO	☐ 1 YES	
3-4.	Reported LDL-C from this draw	___ ___ ___ FLab_LDL	☐ 1 MG/DL FLab_LDLUnits ☐ 2 MMOL/L	

AIM-HIGH

CARDIAC ENZYMES

SITE ID: _____ _____ PATIENT ID: ___ ___ ___

Patient Initials: ___ ___ ___ ____

INSTRUCTIONS: Fill out this form each time a cardiac enzyme measurement is taken. Table Name: ENZ

If the enzymes were taken due to a possible ACS event be sure to submit all documenting materials to Axio Research as soon as possible and fill out all the additional forms related to the event.

1.	Date enzymes were drawn	ENZ_Date ___ ___ / ___ ___ / ___ ___ ___ ___ Use (MM / DD / YYYY)
2-3.	Time enzymes were drawn	ENZ_TimeHH ___ ___ : ENZ_TimeMin ___ ___ Use 24 hour clock
4-5.	CK	ENZ_CK ___ ___ ___ ENZ_CKUnit ☐1 U/L ☐2 MLU/ML ☐3 UKAT/L
6-7.	The lab's CK upper limit of normal	ENZ_CK_ULN ___ ___ ___ ENZ_CK_ULNUnit ☐1 U/L ☐2 MLU/ML ☐3 UKAT/L
8-9.	CK-MB	ENZ_CKMB ___ ___ ___ ENZ_CKMBUnit ☐0 NG/ML ☐1 UG/L ☐2 % ☐3 U/L ☐4 MLU/ML ☐5 UKAT/L
10-11.	The lab's CK-MB upper limit of normal	ENZ_CKMB_ULN ___ ___ ___ ENZ_CKMB_ULNUnit ☐0 NG/ML ☐1 UG/L ☐2 % ☐3 U/L ☐4 MLU/ML ☐5 UKAT/L
12-13.	Troponin	ENZ_Trop ___ ___ ___ ENZ_TropUnit ☐1 NG/ML ☐2 UG/L
14-15.	The lab's Troponin upper limit of normal	ENZ_Trop_ULN ___ ___ ___ ENZ_Trop_ULNUnit ☐1 NG/ML ☐2 UG/L

AIM-HIGH

CNS EVENT

SITE ID: _____ _____ PATIENT ID: ___ ___ ___

Patient Initials: ___ ___ ___ ____

INSTRUCTIONS: Fill this form out if the patient is admitted for evaluation/treatment of any possible CNS Event (Stroke, TIA, etc.)

BE SURE TO SUBMIT ALL DOCUMENTING MATERIALS TO AXIO RESEARCH AS SOON AS POSSIBLE.

Table Name: CNS

1.	Give the start date for event / symptom CNS_symDt	___ ___/___ ___/___ ___ ___ ___ USE (MM/DD/YYYY)
2.	Primary etiology: CNS_Type	☐ 1 ISCHEMIC STROKE ☐ 3 TRANSIENT ISCHEMIC ATTACK ☐ 2 PRIMARY HEMORRHAGIC STROKE ☐ 4 UNABLE TO DETERMINE WHETHER ISCHEMIC OR HEMORRHAGIC
3.	Did the event/condition require hospitalization?	☐ 0 NO CNS_hospital ☐ 1 YES
4.	If yes, Date of admission CNS_admDt	___ ___/___ ___/___ ___ ___ ___ USE (MM/DD/YYYY)
5.	If yes, Date of discharge CNS_discDt	___ ___/___ ___/___ ___ ___ ___ USE (MM/DD/YYYY)
6.	Did symptoms persist for more than 24 hrs?	☐ 0 NO CNS_24Hr ☐ 1 YES
7.	CT obtained CNS_CT	☐ 0 NO ☐ 1 YES
8.	If yes, Date of CT scan CNS_CTDt	___ ___/___ ___/___ ___ ___ ___ USE (MM/DD/YYYY)
9.	MRI obtained CNS_MRI	☐ 0 NO ☐ 1 YES
10.	If yes Date of MRI scan CNS_MRIDt	___ ___/___ ___/___ ___ ___ ___ USE (MM/DD/YYYY)
11.	Cardiac Echo obtained CNS_Echo	☐ 0 NO ☐ 1 YES
12.	If yes Date of Cardiac echo CNS_EchoDt	___ ___/___ ___/___ ___ ___ ___ USE (MM/DD/YYYY)
13.	Carotid Doppler obtained CNS_Doppler	☐ 0 NO ☐ 1 YES
14.	If yes Date of Carotid Dopper exam CNS_DopplerDt	___ ___/___ ___/___ ___ ___ ___ USE (MM/DD/YYYY)
15.	MRA/Angiography obtained CNS_MRA	☐ 0 NO ☐ 1 YES
16.	If yes Date of MRA/Angiography CNS_MRADt	___ ___/___ ___/___ ___ ___ ___ USE (MM/DD/YYYY)

Neuroimaging studies demonstrate:

1. No neuroimaging evidence of acute cerebral infarction (or no neuroimaging performed) [noinfarct]
    1) Yes
    2) No
2. Neuroimaging evidence of acute cerebral infarction on MRI DWI images [Infarct_MRIDWI]
    1) Yes
    2) No
3. Neuroimaging evidence of acute cerebral infarction on MRI T2/Flair (or MRI sequence not specified) [infarctt2flair]
    1) Yes
    2) No
4. Neuroimaging evidence of acute cerebral infarction on CT brain [infarctCT]
    1) Yes
    2) No

AIM-HIGH

CONCOMITANT MEDICATIONS

SITE ID: _____ _____ PATIENT ID: ___ ___ ___

Patient Initials: ___ ___ ___ ____

Table Name: CM

INSTRUCTIONS: Please complete this form noting all medications the patient is routinely taking at the time of this visit. See Manual of Operations for typical drugs in each class.

	Visit	☐ BASELINE ☐ 12 MONTHS ☐ 24 MONTHS ☐ 36 MONTHS ☐ 48 MONTHS		
1.	Beta-blockers	CM_Beta	☐ 0 NO	☐ 1 YES
2.	ACE inhibitors	CM_Ace	☐ 0 NO	☐ 1 YES
3.	Angiotensin II receptor blockers	CM_ATII	☐ 0 NO	☐ 1 YES
4.	Calcium channel blockers	CM_CCB	☐ 0 NO	☐ 1 YES
5.	Diuretics	CM_Diu	☐ 0 NO	☐ 1 YES
6.	Digitalis preparations	CM_Digitalis	☐ 0 NO	☐ 1 YES
7.	Nitrates	CM_Nit	☐ 0 NO	☐ 1 YES
8.	Warfarin or heparin analog	CM_Warfarin	☐ 0 NO	☐ 1 YES
9.	Aspirin (regularly)	CM_Aspirin	☐ 0 NO	☐ 1 YES
10.	NSAIDs (regularly)	CM_NSAID	☐ 0 NO	☐ 1 YES
11.	Cox-2 inhibitors	CM_Cox2	☐ 0 NO	☐ 1 YES
12.	Clopidogrel (Plavix)	CM_Plavix	☐ 0 NO	☐ 1 YES
13.	Metformin	CM_Metformin	☐ 0 NO	☐ 1 YES
14.	Thiazolidinediones (example: rosiglitazone)	CM_TZD	☐ 0 NO	☐ 1 YES
15.	Sulfona Urea	CM_SulU	☐ 0 NO	☐ 1 YES
16.	Insulin	CM_Insulin	☐ 0 NO	☐ 1 YES
17.	Other Diabetes Treatments	CM_OtDiab	☐ 0 NO	☐ 1 YES
18.	Hormone replacement therapy	CM_HRT	☐ 0 NO	☐ 1 YES
19.	If yes to HRT, Estrogens	CM_HRTes	☐ 0 NO	☐ 1 YES
20.	If yes to HRT, Progestins	CM_HRTpro	☐ 0 NO	☐ 1 YES
21.	Corticosteroids (other than topical)	CM_Cort	☐ 0 NO	☐ 1 YES
22.	Antibacterial: - erythromycin* (Erythrocin); clarithromycin* (Bioxin)	CM_Antibac	☐ 0 NO	☐ 1 YES
23.	Nefazodone* (Serzone)	CM_Serzone	☐ 0 NO	☐ 1 YES
24.	Antifungal:- fluconazole* (Diflucan); itraconazole* (Sporonax); ketoconazole* (Nizoral)	CM_Antifun	☐ 0 NO	☐ 1 YES
25.	Fibric acid derivative:- gemfibrozil* (Lopid); fenofibrate* (Tricor)	CM_Fibric	☐ 0 NO	☐ 1 YES
26.	Cyclosporine* (Sandimmune)	CM_Cyclo	☐ 0 NO	☐ 1 YES
27.	High dose vitamins (not multi-vitamin)	CM_HighVit	☐ 0 NO	☐ 1 YES
28	If yes, was the patient taking > 400 IU of vitamin E Or >500mg of vitamin C?	CM_Vit_C_E	☐ 0 NO	☐ 1 YES
29	Was the patient taking niacin or nicotinic acid?	CM_Niacin	☐ 0 NO	☐ 1 YES

SITE ID: _____ _____ PATIENT ID: ___ ___ ___

Patient Initials: ___ ___ ___ ____

CONCOMITANT MEDICATIONS

30	If taking niacin, daily dose	CM_NiacDose	☐ 1 500 MG	☐ 2 1,000 MG
31	Fish oil or fish oil derivatives or any n-3 fatty acids	CM_FishOil	☐ 0 NO	☐ 1 YES

Drugs listed in questions 22-31 are excluded. Follow up with the patient and his/her physician to see if they can be discontinued.

AIM-HIGH

DEATH

SITE ID: _____ _____ PATIENT ID: ___ ___ ___

Patient Initials: ___ ___ ___ ____

INSTRUCTIONS: Fill this form out if the patient dies at any time during the study.

Table Name: DTH

BE SURE TO SUBMIT ALL DOCUMENTING MATERIALS (if any) TO AXIO RESEARCH AS SOON AS POSSIBLE.

1.	Date of death *(mm/dd/yyyy)* DTH_Date	___ ___/ ___ ___/ ___ ___ ___ ___ USE (MM / DD / YYYY)
2.	What was the presumed cause of death? DTH_Cause	☐ 1 CARDIAC ☐ 2 VASCULAR, NON-CARDIAC ☐ 3 NON-CARDIOVASCULAR
3.	For Cardiac, please specify DTH_CardiacCause	☐ 1 ISCHEMIC ☐ 2 EMD ☐ 3 CHF ☐ 4 BRADYARRHYTHMIA /ASYSTOLE ☐ 5 VT/VF ☐ 6 NOT DETERMINED
4.	For vascular, non-cardiac, please specify DTH_VasCause	☐ 1 STROKE ☐ 2 NON-CNS HEMORRHAGE ☐ 3 PULMONARY EMBOLISM ☐ 4 NOT DETERMINED ☐ 5 OTHER
5.	If other, please specify DTH_VasCauseOth	_____ _____ _____ _____
6.	For non-cardiovascular, please specify DTH_NonCause	☐ 1 CANCER ☐ 2 PNEUMONIA ☐ 3 OTHER LUNG DISEASE ☐ 4 INFECTION/SEPSIS ☐ 5 NOT DETERMINED ☐ 6 OTHER
7.	If other, please specify DTH_NonCauseOth	_____ _____ _____ _____
8.	Was the patient in the emergency room or hospitalized at the time of death?	☐ 0 NO DTH_Hospital ☐ 1 YES
9.	Was an autopsy performed?	☐ 0 NO DTH_Autopsy ☐ 1 YES
10.	Did the death occur within 30 days of undergoing cardiac surgery or a revascularization procedure?	☐ 0 NO DTH_Revas ☐ 1 YES

AIM-HIGH

DEMOGRAPHICS

SITE ID: _____ _____ PATIENT ID: ___ ___ ___

Patient Initials: ___ ___ ___ ____

INSTRUCTIONS: Please complete at the screening visit. Table Name: Demo

1.	Visit date Demo_VisDt	___ ___ / ___ ___ / ___ ___ ___ ___ Use (MM / DD / YYYY)
2.	Birth date Demo_DOB	___ ___ / ___ ___ / ___ ___ ___ ___ Use (MM / DD / YYYY)
3.	Age Demo_Age	___ ___ (calculated on computer)
4.	Gender Demo_Sex	☐ 1 MALE ☐ 0 FEMALE
5.	Ethnicity Demo_Ethn	☐ 1 NOT HISPANIC OR LATINO ☐ 2 HISPANIC OR LATINO
6.	What does the patient consider his/her predominant race? Demo_Race	☐ 1 AMERICAN INDIAN / ALASKA NATIVE / ABORIGINAL CANADIAN ☐ 2 ASIAN ☐ 3 BLACK / AFRICAN AMERICAN ☐ 4 NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER ☐ 5 WHITE ☐ 8 MULTI-RACIAL OR OTHER
7.	Tobacco use? Demo_Smoke	☐ 1 NEVER USED ☐ 3 SMOKELESS TOBACCO USER ☐ 2 CURRENT SMOKER ☐ 4 FORMER USER (QUIT MORE THAN 1 YEAR AGO)
8.	If tobacco user, estimate the number of pack years of consumptions	___ ___ ___ Demo_TobNm
9.	Does the patient consume alcohol?	☐ 0 NO Demo_Alcohol ☐ 1 YES
10.	If yes, what is the average number of drinks consumed per week? Demo_Alcnum	☐ 1 LESS THAN 3 DRINKS ☐ 2 3-7 DRINKS ☐ 3 8-15 DRINKS ☐ 4 MORE THAN 15
11.	What is the patient's current employment status? Demo_Employ	☐ 1 FULL TIME ☐ 5 DISABLED ☐ 2 PART TIME ☐ 3 RETIRED ☐ 6 UNEMPLOYED ☐ 4 NOT WORKING OUTSIDE THE HOME-BY CHOICE ☐ 9 NOT PROVIDED
12.	What field best describes the patient's work category? Demo_Job	☐ 1 MANAGEMENT ☐ 7 SKILLED LABOR ☐ 2 PROFESSIONAL ☐ 8 GENERAL LABOR ☐ 3 BUSINESS/FINANCIAL ☐ 9 FARMER ☐ 4 IT SPECIALIST ☐ 10 SELF-EMPLOYED BUSINESS ☐ 5 SALES ☐ 11 POLICE/MILITARY ☐ 6 CLERICAL ☐ 12 NOT PROVIDED
13.	Education Level Demo_Edu	☐ 1 LESS THAN HIGH SCHOOL ☐ 2 HIGH SCHOOL GRAD (OR GED) ☐ 3 SOME COLLEGE/UNIVERSITY ☐ 4 COLLEGE/UNIVERSITY GRADUATE ☐ 5 POST COLLEGE/UNIVERSITY DEGREE ☐ 9 NOT PROVIDED

AIM-HIGH

DRUG DOSE ADJUSTMENT

SITE ID: _____ _____ PATIENT ID: ___ ___ ___

Patient Initials: ___ ___ ___ ____

Table Name: DAdj

INSTRUCTIONS: Fill this form for any visit where the dose levels for the patient need to be adjusted.

1.	Date of dose adjustment DAdj_VisDt	___ ___/___ ___/___ ___ ___ ___ USE (MM/DD/YYYY)
2.	Was the dose of niaspan/placebo adjusted or drug discontinued? DAdj_DoseAdj	☐ 0 NO ☐ 1 DISCONTINUED ☐ 2 YES, LOWERED ☐ 3 YES, RAISED
3.	What is new dose level? Dadj_NiaspanDoseNewLevel	☐ 1 500 MG/DAY ☐ 2 1,000 MG/DAY ☐ 3 1,500 MG/DAY ☐ 4 2,000 MG/DAY
4.	If niaspan dose adjusted or discontinued, what was the primary reason? **Note change in reason choices – coated product!** DAdj_NiaspanDoseAdjReason	☐ 1 FLUSHING, ITCHING ☐ 2 LIVER FUNCTION TEST ABNORMALITY ☐ 3 RESUME HIGHER DOSE ☐ 4 PATIENT REQUEST ☐ 5 NON-STUDY PHYSICIAN REQUEST ☐ 6 OTHER CLINICAL REASON TO LOWER DOSE ☐ 7 INCREASED GLUCOSE ☐ 8 GI SYMPTOMS ☐ 9 COATED PRODUCT
5.	If other reason, please specify DAdj_DoseAdjSpcReason	_____ _____
6.	Was the dose of Zocor (simvastatin) adjusted or discontinued? DAdj_StatinDoseAdj	☐ 0 NO ☐ 1 DISCONTINUED ☐ 2 YES, LOWERED ☐ 3 YES, RAISED
7.	What is new dose level? DAdj_StatinDoseNewLevel	☐ 5 5 MG/DAY ☐ 1 10 MG/DAY ☐ 2 20 MG/DAY ☐ 3 40 MG/DAY ☐ 6 60 MG/DAY ☐ 4 80 MG/DAY
8.	If yes, what was the primary reason? DAdj_StatinDoseAdjReason	☐ 1 LOWER DOSE FOR ADVERSE CLINICAL SYMPTOMS ☐ 2 RAISE DUE TO HIGH LDL ☐ 3 PATIENT REQUEST ☐ 4 NON-STUDY PHYSICIAN REQUEST ☐ 5 OTHER REASON FOR DOSE ADJUSTMENT ☐ 6 LOWER DUE TO LOW LDL
9.	If other reason, please specify DAdj_StatinDoseAdjSpcReason	_____ _____
10.	If not on Zocor, is patient taking another statin? DAdj_AnotherStatin	☐ 0 NO ☐ 1 YES
11.	If yes, which? DAdj_StatinType	☐ 1 Atorvastatin (Lipitor®) ☐ 2 Fluvastatin (Lescol®) ☐ 3 Lovastatin (Altocor® or Mevacor®) ☐ 4 Pravastatin (Pravacol®) ☐ 5 Rosuvastatin (Crestor®) ☐ 7 Other

AIM-HIGH

SITE ID: _____ _____ PATIENT ID: ___ ___ ___

Patient Initials: ___ ___ ___ ____

DRUG DOSE ADJUSTMENT

12.	If other, please specify DAdj_StatinOth	_____
13.	What dose level of statin (in mgs) is the patient taking? DAdj_StatinDose	____ ____ MGS/DAY
14.	What is current ezetimibe use? DAdj_EzDoseAdj	☐ 1 NOT USED AT THIS TIME ☐ 2 ADDED AT THIS VISIT ☐ 3 CONTINUING USE ☐ 4 DISCONTINUED THIS VISIT
15.	If discontinued, what was the primary reason? DAdj_EzDoseAdjReason	☐ 1 PATIENT REQUEST ☐ 2 NON-STUDY PHYSICIAN REQUEST ☐ 3 OTHER REASON FOR DOSE ADJUSTMENT ☐ 4 LIVER FUNCTION TEST ABNORMALITY
16.	If other reason, please specify DAdj_EzDoseAdjSpcReason	_____ _____

AIM-HIGH

DRUG ADHERENCE

SITE ID: _____ _____ PATIENT ID: ___ ___ ___

Patient Initials: ___ ___ ___ ____

INSTRUCTIONS: Fill this form at every in-office visit starting at the 3 Month visit.

Table Name: DAdh

1.	Visit Date *(mm/dd/yyyy)* DAdh_VisDt	___ ___ / ___ ___ / ___ ___ ___ ___ USE (MM / DD / YYYY)
2.	What was the kit number for the drug returned? DAdh_KitNum	___ ___ ___ ___ ___ ___ ___
3.	Was another kit returned? If so, please list the kit number here. DAdh_KitNum2	___ ___ ___ ___ ___ ___ ___
4.	What date did the patient start taking the drugs in this kit? DAdh_KitNumDt	___ ___ / ___ ___ / ___ ___ ___ ___ USE (MM / DD / YYYY)
5.	Question removed per Amendment 3. DAdh NiaspanDose	
6.	Question removed per Amendment 3. DAdh_StatinDose	
7.	Approximate number of Niaspan/Placebo tablets returned or otherwise not taken (e.g. lost)? DAdh_Niaspan_Return	___ ___ ___
	Returned Niaspan/Placebo should be destroyed – See Manual of Operations	
8.	Approximate number of Zocor (simvastatin) tablets returned or otherwise not taken (e.g. lost)?	DAdh_Statin_Return ___ ___ ___
9.	Was ezetimibe prescribed?	☐ 0 NO DAdh_Ezt ☐ 1 YES
10.	If on ezetimibe, approximate number of ezetimibe tablets returned or otherwise not taken (e.g. lost)?	DAdh_Ezt_Return ___ ___ ___
11.	Did patient report taking drugs as prescribed?	☐ 0 NO DAdh_Adhere ☐ 1 YES
12.	If no, was it the Niaspan/Placebo?	☐ 0 NO DAdh_NoAdhereNia ☐ 1 YES
13.	If no, was it the Zocor (simvastatin)?	☐ 0 NO DAdh_NoAdhereZocor ☐ 1 YES
14.	If no, was it the ezetimibe?	☐ 0 NO DAdh_NoAdhereEze ☐ 1 YES
15.	If medications were not taken as prescribed or if adherence is suspected to be poor (less than 75%), what was the primary reason for poor adherence? DAdh_BadWhy	☐ 0 N/A, GOOD ADHERENCE ☐ 1 ADVERSE CLINICAL SYMPTOMS ☐ 2 PATIENT FORGETFUL ☐ 3 NON-STUDY PHYSICIAN RECOMMENDED DIFFERENT DOSE ☐ 4 PATIENT DECISION ☐ 5 SUPPLY RAN OUT ☐ 6 UNKNOWN ☐ 7 OTHER

DRUG ADHERENCE

SITE ID: _____ _____ PATIENT ID: ___ ___ ___

Patient Initials: ___ ___ ___ ____

16.	If other reason for poor adherence, please describe **DAdh_BadSpcWhy**	_____ _____ _____

AIM-HIGH

DRUG DISPENSING

SITE ID: _____ _____ PATIENT ID: ___ ___ ___

Patient Initials: ___ ___ ___ ____

INSTRUCTIONS: Complete this form at randomization and all in-clinic visits after randomization or whenever Blinded Study Drug Kits, Zocor (simvastatin) or Ezetimibe bottles are dispensed.

Table Name: Disp

	Visit	☐ RANDOMIZATION ☐ 3 MONTHS ☐ 6 MONTHS ☐ 9 MONTHS ☐ 12 MONTHS ☐ 15 MONTHS ☐ 18 MONTHS ☐ 21 MONTHS ☐ 24 MONTHS ☐ 27 MONTHS ☐ 30 MONTHS ☐ 33 MONTHS ☐ 36 MONTHS ☐ 39 MONTHS ☐ 42 MONTHS ☐ 45 MONTHS ☐ 48 MONTHS ☐ 51 MONTHS ☐ 54 MONTHS ☐ 57 MONTHS ☐ _____
1	Visit Date *(mm/dd/yyyy)*	Disp_VstDt ___ ___ / ___ ___ / ___ ___ ___ ___ USE (MM / DD / YYYY)
2	What daily dose of Niaspan/Placebo will be dispensed? Disp_Dose	☐ 0 NONE DISPENSED ☐ 3 1,500 MG/DAY ☐ 1 500 MG/DAY ☐ 4 2,000 MG/DAY ☐ 2 1,000 MG/DAY
3	Study drug kit number dispensed:	Disp_Kit ___ ___ ___ ___ ___ ___ ___
4	If the next study kit was also provided at this visit, give the kit number:	Disp_Kit2 ___ ___ ___ ___ ___ ___ ___
5	What daily dose of Zocor (simvastatin) will be dispensed? Disp_StatinDose	☐ 0 NONE DISPENSED ☐ 7 30 MG ☐ 5 5 MG ☐ 3 40 MG ☐ 1 10 MG ☐ 6 60 MG ☐ 2 20 MG ☐ 4 80 MG
NUMBER OF BOTTLES OF ZOCOR (SIMVASTATIN) DISPENSED.		
6	Number of 10 mg Zocor (simvastatin) bottles dispensed	Disp_StatinBottles_10 _____
7	Number of 20 mg Zocor (simvastatin) bottles dispensed	Disp_StatinBottles_20 _____
8	Number of 40 mg Zocor (simvastatin) bottles dispensed	Disp_StatinBottles_40 _____
9	Number of ezetimibe bottles dispensed	Disp_Ezetimibe _____

AIM-HIGH

ECG

SITE ID: _____ _____ PATIENT ID: ___ ___ ___

Patient Initials: ___ ___ ___ ____

INSTRUCTIONS: Fill this form at the Baseline (start of Run-In) visit, 12, 24, 36, 48, and 60-month visit. Also, fill this form out EVERY time the patient has an ECG done for any reason.

PLEASE REMEMBER TO SEND THE ORIGNAL ECG TRACES TO THE CORE ECG LAB AS SOON AS POSSIBLE.

Table Name: ECG

1.	What was the reason the ECG was taken? ECG_reason	☐ 1 BASELINE HISTORY ☐ 3 CARDIAC EVENT ☐ 2 SCHEDULED FOLLOW-UP ☐ 4 OTHER UNSCHEDULED EVENT
2.	Date of ECG *(mm/dd/yyyy)* ECG_date	___ ___ / ___ ___ / ___ ___ ___ ___ USE (MM / DD / YYYY)
3.	Time of ECG- hour (use 24 hour clock) ECG_timeHr ECG_TimeMin	___ ___ : ___ ___ (USE 24 HOUR CLOCK)

AIM-HIGH

SITE ID: _____ _____ PATIENT ID: ___ ___ ___

Patient Initials: ___ ___ ___ ____

END OF BLINDED TREATMENT PHASE

Table Name: Term

INSTRUCTIONS: **Fill this form out at the end of blinded treatment phase for all randomized patients.**

1.	Visit Date *(mm/dd/yyyy)*	Term_Date ___ ___ / ___ ___ / ___ ___ ___ ___ Use (MM / DD /YYYY)		
2.	What was the primary reason for withdrawal from the study? ☐ If death, complete Death Event form and submit documenting materials. If lost, contact the Coordinating Center for instructions.	☐ 1 END OF STUDY ☐ 2 PROTOCOL VIOLATION ☐ 3 PATIENT REQUEST ☐ 4 NON-STUDY PHYSICIAN REQUEST ☐ 5 DEATH ☐ 6 LOST TO FOLLOW-UP Term_Reason		
3.	Was the patient on blinded study drug (Niacin/Placebo) at the end of the trial (May 24th, 2011)?	☐ 0 NO	☐ 1 YES Term_Drug	
4.	Will patient remain on lipid lowering/modifying treatments? If yes, which one(s)?	☐ 0 NO	☐ 1 YES Term_LipidTx	
5.	Statins	☐ 0 NO	☐ 1 YES	Term_Statin
6.	Bile Acid sequestrates	☐ 0 NO	☐ 1 YES	Term_BileAcid
7.	Nicotinic acid (e.g. extended release niacin (Niaspan), combination statin with extended release niacin(Advicor))	☐ 0 NO	☐ 1 YES Term_Nicotin	
8.	Fibric acid derivative (e.g. gemfibrozil (Lopid); fenofibrate (Tricor))	☐ 0 NO	☐ 1 YES Term_Fibric	
9.	Cholesterol absorption inhibitors	☐ 0 NO	☐ 1 YES	Term_Absorb
10.	Other lipid modifying agents	☐ 0 NO	☐ 1 YES	Term_OtherDrug
11.	Therapeutic lifestyle changes (diet & exercise) ONLY	☐ 0 NO	☐ 1 YES Term_TLC	
12.	Thinking back to when the participant was enrolled, how long had they been taking a statin *PRIOR to enrollment in AIM-HIGH?*	☐ 0 NOT ON A STATIN AT ENTRY ☐ 1 < 1 YEAR PRIOR TO ENROLLMENT ☐ 2 1 – 5 YEARS PRIOR TO ENROLLMENT ☐ 3 > 5 YEARS PRIOR TO ENROLLMENT Term_Duration		
13.	Please ask the participant to make their best guess regarding which therapy they were assigned:	☐ 1 ACTIVE NIASPAN	☐ 2 PLACEBO	☐ 3 NO IDEA Term_Therapy
14.	What is *your* (Research Coordinator) best guess regarding which therapy the participant was assigned:	☐ 1 ACTIVE NIASPAN	☐ 2 PLACEBO	☐ 3 NO IDEA Term_TherapyRC

AIM-HIGH

EVENT NOTIFICATION

SITE ID: _____ _____ PATIENT ID: ___ ___ ___

Patient Initials: ___ ___ ___ ____

INSTRUCTIONS: Fill this form out as soon as you learn that a patient has experienced any study event.

This is <u>not</u> to be filled out if the patient experiences an Adverse Event (see the Adverse Event form). Only use this form for the specific events listed below in Question #2.

Please complete and enter all relevant supplemental forms, as indicated below.

BE SURE TO SUBMIT ALL DOCUMENTING MATERIALS TO AXIO RESEARCH AS SOON AS POSSIBLE.

1.	Date of event *(mm/dd/yyyy)* `EvntNot_EvtDt`	___ ___ / ___ ___ / ___ ___ ___ ___ USE (MM / DD / YYYY)
2.	Event type `EvntNot_Type`	☐ 1 ACS ☐ 2 CNS ☐ 3 REVASCULARIZATION ☐ 4 DEATH ☐ 5 RULED NOT AN EVENT
3.	If ACS Event, which of the following? (If applicable, complete ACS Event, ECG and Cardiac Enzyme forms and submit documenting materials) `EvntNot_ACS`	☐ 1 MI ☐ 2 UNSTABLE ANGINA ☐ 3 NO DOCUMENTED ISCHEMIA
4.	If CNS Event, which of the following? (If yes, complete CNS Event form and submit documenting materials) `EvntNot_CNS`	☐ 1 ISCHEMIC STROKE ☐ 2 PRIMARY HEMORRHAGIC STROKE ☐ 3 TRANSIENT ISCHEMIC ATTACK ☐ 4 UNABLE TO DETERMINE WHETHER ISCHEMIC OR HEMORRHAGIC
5.	If Revascularization, which of the following? `EvntNot_Revasc` (If yes, complete Revascularization form and submit documenting materials)	☐ 1 CARDIAC ☐ 2 CEREBROVASCULAR ☐ 3 PERIPHERAL

AIM-HIGH

EXCLUSION CRITERIA

SITE ID: _____ _____ PATIENT ID: ___ ___ ___

Patient Initials: ___ ___ ___ ____

Table Name: Exc

INSTRUCTIONS: Please complete at the Screening Visit. If you select YES for any of the questions below, the patient is NOT eligible for the study.

Exc_ACS	1.	Has the patient been hospitalized for acute coronary syndrome with discharge within 4 weeks prior to planned enrollment?	☐0 NO ☐1 YES
Exc_CAB	2.	Has the patient had CABG surgery within the past 5 years without recent ACS? (recent ≤ 1 year)	☐0 NO ☐1 YES
Exc_PCI	3.	Has the patient had a PCI within the past 4 weeks?	☐0 NO ☐1 YES
Exc_stroke8wk	4.	Has the patient had a stroke or TIA within the past 8 weeks?	☐0 NO ☐1 YES
Exc_Glucometer	5.	Is the patient diabetic and unable to or refuses to use a glucometer for home monitoring of glucose?	☐0 NO ☐1 YES
Exc_PostMIvas	6.	Is the need/likelihood of urgent revascularization is high?	☐0 NO ☐1 YES
Exc_LfCAD	7.	Does the patient have left main coronary disease ≥ 50% and no prior CABG?	☐0 NO ☐1 YES
Exc_Ejc	8.	Is the patient's ejection fraction <30%?	☐0 NO ☐1 YES
Exc_Unresp	9.	Does the patient have cardiogenic shock, pulmonary edema, angina, or CHF unresponsive to standard medical therapy? (CCS class IV)	☐0 NO ☐1 YES
Exc_CVD	10.	Does the patient have concomitant valvular heart disease likely to require surgery or affect prognosis during follow-up period?	☐0 NO ☐1 YES
Exc_CardMy	11.	Does the patient have congenital or primary cardiomyopathy likely to affect prognosis during follow-up period?	☐0 NO ☐1 YES
Exc_ICD	12.	Has the patient experienced resuscitated out-of-hospital sudden death or symptomatic sustained or non-sustained ventricular tachycardia and does not now have an implantable cardioverter-defibrillator (ICD)?	☐0 NO ☐1 YES
Exc_Hyper	13.	Does the patient have significant systemic hypertension (BP>200/100 mm Hg) unresponsive to medical therapy?	☐0 NO ☐1 YES
Exc_Peptic	14.	Does the patient have active peptic ulcer disease?	☐0 NO ☐1 YES
Exc_Meds	15.	Must the patient continue with any of the excluded medications?	☐0 NO ☐1 YES
Exc_preg	16.	**If the patient is female**, is she pregnant or likely to become pregnant (i.e. premenopausal and not using birth control)?	☐0 NO ☐1 YES ☐3 N/A (MALE)

Continue 2nd

AIM-HIGH

EXCLUSION CRITERIA

SITE ID: _____ _____ PATIENT ID: ___ ___ ___

Patient Initials: ___ ___ ___ ____

Exc_comorb	17.	Does the patient have any significant co-morbidity likely to cause death in the 3-5 year follow-up period?	☐ 0 NO	☐ 1 YES
Exc_HIV	18.	Does the patient have AIDS or active HIV infection?	☐ 0 NO	☐ 1 YES
Exc_abuse	19.	Does the patient have a significant active history of substance abuse within the previous 5 years?	☐ 0 NO	☐ 1 YES
Exc_Clintrial	20.	Is the patient currently participating in another long-term clinical trial?	☐ 0 NO	☐ 1 YES
Exc_patient	21.	Is the patient unwilling to participate?	☐ 0 NO	☐ 1 YES
Exc_Physician	22.	Is the physician or other non-study physicians unwilling to allow patient to participate?	☐ 0 NO	☐ 1 YES
	LAB value Exclusions			
Exc_Glu	23.	Is the patient's fasting glucose >180 mg/dL or hemoglobin A_1C >9.0%?	☐ 0 NO	☐ 1 YES
Exc_Liver	24.	Does the patient have AST or ALT > 2 times upper limit of normal or active liver disease?	☐ 0 NO	☐ 1 YES
Exc_Gout	25.	Does the patient have a recent history of acute gout or uric acid > 7.0 mg/dL despite therapy with allopurinol?	☐ 0 NO	☐ 1 YES
Exc_creat	26.	Does the patient have chronic renal insufficiency with creatinine ≥ 2.5 mg/dl?	☐ 0 NO	☐ 1 YES

AIM-HIGH

FOLLOW-UP

SITE ID: _____ _____ PATIENT ID: ___ ___ ___

Patient Initials: ___ ___ ___ ____

Table Name: FoL

INSTRUCTIONS: Please complete at each Follow-up visit or Follow-up phone call.

	Visit	☐ 2 WEEK RUN IN	☐ 9 MONTHS	☐ 27 MONTHS	☐ 45 MONTHS
		☐ 2 WEEK	☐ 12 MONTHS	☐ 30 MONTHS	☐ 48 MONTHS
		☐ 1 MONTH	☐ 15 MONTHS	☐ 33 MONTHS	☐ 52 MONTHS
		☐ 2 MONTHS	☐ 18 MONTHS	☐ 34 MONTHS	☐ 54 MONTHS
		☐ 3 MONTHS	☐ 21 MONTHS	☐ 39 Months	☐ 57 MONTHS
		☐ 6 MONTHS	☐ 24 MONTHS	☐ 42 Months	☐ 60 MONTHS
1.	Date of visit or phone call Fol_Date	___ ___ / ___ ___ / ___ ___ ___ ___ USE (MM / DD / YYYY)			
2.	In-office Visit or Phone call? Fol_VisitType	☐ 1 IN-OFFICE	☐ 2 PHONE CALL		
3.	Reason for follow-up Fol_Reason	☐ 1 SCHEDULED ☐ 2 UNSCHEDULED FOR SIDE EFFECT ☐ 3 UNSCHEDULED FOR DOSE ADJUSTMENT			
4.	Was study drug dose adjusted or discontinued? (If yes, please complete Dose Adjustment form) Fol_DrugDC	☐ 0 NO	☐ 1 YES		
Screen Patient for Possible Efficacy Endpoints:					
5.	MI: (If yes, complete ACS Event form and submit documenting materials) Fol_MI	☐ 0 NO	☐ 1 YES		
6.	Stroke: (If yes or possible, complete CNS Event form and submit documenting materials) Fol_Stroke	☐ 0 NO	☐ 1 YES – WITH DOCUMENTATION	☐ 2 POSSIBLE – YES TO STROKE SYMPTOM QUESTION(S)	
7.	Hospitalization for evaluation of acute coronary syndrome (ACS): (If yes, complete ACS Event form and submit documenting materials) Fol_ACS	☐ 0 NO	☐ 1 YES		
8.	Cardiac revascularization (CABG or PCI): Fol_CardRevasc (If yes, complete Revascularization form.)	☐ 0 NO	☐ 1 YES		
9.	Cerbrovascular revascularization (carotid endarterectomy, carotid PTA): Fol_CerebRevasc (If yes, complete Revascularization form)	☐ 0 NO	☐ 1 YES		
10.	Peripheral revascularization: Fol_PeriphRevasc (If yes, complete Revascularization form)	☐ 0 NO	☐ 1 YES		

Continue 2nd page

AIM-HIGH

FOLLOW-UP

SITE ID: _____ _____ PATIENT ID: ___ ___ ___

Patient Initials: ___ ___ ___ ____

Screen Patient for Possible Adverse Events or Symptoms:

Follow-up as needed

11.	How frequently did the patient experience flushing? Fol_Flush	☐ 1 NO FLUSHING REPORTED ☐ 3 MODERATELY FREQUENTLY (MANY DAYS, BUT NOT EVERY DAY) ☐ 2 INFREQUENTLY (ONLY A FEW TIMES DURING THIS PERIOD) ☐ 4 DAILY (ALMOST EVERY DAY, USUALLY FOLLOWING THE DOSE)
12.	On average, how severe (annoying) were the flushing episodes? Fol_Flush2	☐ 1 NO SYMPTOMS ☐ 3 MODERATE ☐ 2 MILD ☐ 4 SEVERE
13.	Did the patient take aspirin or other analgesic prior to taking the Niaspan or Placebo?	☐ 0 NO Fol_Prior ☐ 1 YES
14.	Was it generally effective in preventing or reducing the incidence or severity of flushing?	☐ 0 NO Fol_Prior2 ☐ 1 YES
15.	Did the patient report any itching? (if yes, note severity) Fol_Itch	☐ 0 NO SYMPTOMS ☐ 2 MODERATE ☐ 1 MILD ☐ 3 SEVERE
16.	Did the patient report any nausea? (if yes, note severity) Fol_Nausea	☐ 0 NO SYMPTOMS ☐ 2 MODERATE ☐ 1 MILD ☐ 3 SEVERE
17.	Did the patient report other gastro-intestinal symptoms (heartburn, gas) associated with the study drugs? (if yes, note severity) Fol_HeartBurn	☐ 0 NO SYMPTOMS ☐ 2 MODERATE ☐ 1 MILD ☐ 3 SEVERE
18.	Did patient report muscle aches or weakness? (if yes, note severity) Fol_Muscle	☐ 0 NO SYMPTOMS ☐ 2 MODERATE ☐ 1 MILD ☐ 3 SEVERE
19.	Did the patient experience fatigue? (if yes, note severity) Fol_Fatigue	☐ 0 NO SYMPTOMS ☐ 2 MODERATE ☐ 1 MILD ☐ 3 SEVERE
20.	Did the patient report any marked changes in eyesight? (if yes, note severity) Fol_Vision	☐ 0 NO SYMPTOMS ☐ 2 MODERATE ☐ 1 MILD ☐ 3 SEVERE
21.	Did the patient report development of gout or severe symptoms of arthritis? (if yes, note severity) Fol_Gout	☐ 0 NO SYMPTOMS ☐ 2 MODERATE ☐ 1 MILD ☐ 3 SEVERE
22.	For diabetic patients, did they use a glucometer? Fol_Diabetic	☐ 0 NOT DIABETIC ☐ 1 NO ☐ 2 YES
23.	Did fasting glucometer measurements rise by more than 15 mg/dl (0.75 mmol/l)?	☐ 0 NO Fol_Glucose ☐ 1 YES

If the answer to questions 19-21, or 23 was yes and these were considered to be possibly or probably related to the study drug, complete the suspected toxicity and Adverse Event forms.

24.	Any other adverse events: (if yes, add events on "Averse Events" page) Fol_AEs	☐ 0 NO ☐ 1 YES

AIM-HIGH

HEALTH CARE UTILIZATION

SITE ID: _____ _____ PATIENT ID: ___ ___ ___

Patient Initials: ___ ___ ___ ____

Table Name: HU

INSTRUCTIONS: Please fill out this form at in-office visits at month 6, 12, 18, 24, 30, 36, 42, 48 and 60 month.

1.	Visit Date *(mm/dd/yyyy)*	HU_Date ___ ___/___ ___/___ ___ ___ ___ USE (MM/DD/YYYY)
2.	Number of outpatient doctor visits to cardiologist, peripheral vascular surgeon or physician, neurologist or family physician/internist for cardiovascular problems since last follow-up contact	HU_Outpatient ___ ___
3.	Number of home health care days of assistance since last follow-up	HU_HomeHealth ___ ___
4.	Number of days in nursing or rehab facility since last follow-up	HU_Rehab ___ ___
5.	What is the patient's current work status? HU_WorkStatus	☐ 1 FULL TIME ☐ 2 PART TIME ☐ 3 RETIRED ☐ 4 NOT WORKING OUTSIDE THE HOME-BY CHOICE ☐ 5 DISABLED ☐ 6 UNEMPLOYED ☐ 9 NOT PROVIDED
6.	Has the patient changed work status since the last follow-up due to health issues?	HU_WorkChg ☐ 0 NO ☐ 1 REDUCED WORK HOURS ☐ 2 QUIT WORKING ☐ 3 INCREASED WORK HOURS
7.	If still working, what number of days was the patient unable to work because of health issues:	HU_WorkLost ___ ___
Mark all (if any) cardiac outpatient procedures done since the last follow-up:		
8.	Cardiac catheterization HU_Cath	☐ 0 NO ☐ 1 YES
9.	Cardioversion HU_Cardiov	☐ 0 NO ☐ 1 YES
10.	Pacemaker implant HU_Pacemaker	☐ 0 NO ☐ 1 YES
11.	Electrophysiology study HU_EP	☐ 0 NO ☐ 1 YES
12.	Transthoracic cardiac echo HU_echo	☐ 0 NO ☐ 1 YES
13.	Transesophageal cardiac echo HU_TEE	☐ 0 NO ☐ 1 YES
14.	Radionuclide scan HU_NucScan	☐ 0 NO ☐ 1 YES
15.	CT scan (cardiac or other) HU_CT	☐ 0 NO ☐ 1 YES
16.	MRI scan (cardiac or other) HU_MRI	☐ 0 NO ☐ 1 YES

AIM-HIGH

HOSPITALIZATION

SITE ID: _____ _____ PATIENT ID: ___ ___ ___

Patient Initials: ___ ___ ___ ____

INSTRUCTIONS: Please fill out this form any time the patient is hospitalized for any reason.

Table Name: HOSP

1.	Date of admission *(mm/dd/yyyy)* **Hosp_AdmDt**	___ ___/___ ___/___ ___ ___ ___ USE (MM/DD/YYYY)	
2.	Date of discharge (mm/dd/yyyy) **Hosp_DischDt**	___ ___/___ ___/___ ___ ___ ___ USE (MM/DD/YYYY)	
3.	Type of admission: **Hosp_ED**	☐ 1 HOSPITAL ☐ 2 EMERGENCY DEPARTMENT ONLY	
4.	Number of days in ICU	_____	**Hosp_ICU**
5.	Admission diagnosis (ICD code)	_____	**Hosp_AdmDx**
6.	Primary discharge diagnosis (ICD code)	_____	**Hosp_DischDx**
7.	Did the patient die during this admission? If yes, complete death form.	☐ 0 NO ☐ 1 YES	**Hosp_Death**
8.	Did patient undergo revascularization during this hospitalization? If yes, complete Revascularization form.	☐ 0 NO ☐ 1 YES	**Hosp_Revasc**
9.	Did patient suffer an MI during this admission? If yes, complete ACS Event form.	☐ 0 NO ☐ 1 YES	**Hosp_MI**
Check if any of the procedures below were performed during this hospital/ER visit.			
10.	Cardiac catheterization	☐ 0 NO ☐ 1 YES	**Hosp_Cath**
11.	Cardioversion	☐ 0 NO ☐ 1 YES	**Hosp_Cardiov**
12.	Pacemaker implant	☐ 0 NO ☐ 1 YES	**Hosp_Pace**
13.	ICD implant	☐ 0 NO ☐ 1 YES	**Hosp_ICD**
14.	Aneurysm resection	☐ 0 NO ☐ 1 YES	**Hosp_Aneur**
15.	Valve repair or replacement	☐ 0 NO ☐ 1 YES	**Hosp_Valve**
16.	Electrophysiology study	☐ 0 NO ☐ 1 YES	**Hosp_EP**
17.	Transthoracic cardiac echo	☐ 0 NO ☐ 1 YES	**Hosp_echo**
18.	Transesophageal cardiac echo	☐ 0 NO ☐ 1 YES	**Hosp_TEE**
19.	Radionuclide scan	☐ 0 NO ☐ 1 YES	**Hosp_NucScan**
20.	CT scan (cardiac or other)	☐ 0 NO ☐ 1 YES	**Hosp_CT**
21.	MRI scan (cardiac or other)	☐ 0 NO ☐ 1 YES	**Hosp_MRI**

AIM-HIGH

MEDICAL HISTORY

SITE ID: _____ _____ PATIENT ID: ___ ___ ___

Patient Initials: ___ ___ ___ ____

INSTRUCTIONS: Fill this form at the Baseline visit.
Based on all available medical records, please record the history for each condition. Answer "yes" only if probable or certain.

Table Name: Hx

Cardiovascular Medical History

1.	Angina HX_Angina	☐ 0 NO	☐ 1 YES
2.	Acute coronary syndrome (ACS) HX_ACS	☐ 0 NO	☐ 1 YES
3.	Date of most recent hospitalization for ACS - month HX_ACSdateMM	___ ___	
4.	Date of most recent hospitalization for ACS - year HX_ACSdateYY	___ ___ ____ ____	
5.	Myocardial infarction (MI) Hx_MI	☐ 0 NO	☐ 1 YES
6.	Date of most recent MI - month HX_MIdateMM	___ ___	
7.	Date of most recent MI - year HX_MIdateYY	___ ___ ____ ____	
8.	Ventricular arrhythmia Hx_VenArr	☐ 0 NO	☐ 1 YES
9.	Atrial fibrillation Hx_Afib	☐ 0 NO	☐ 1 YES
10.	Congestive heart failure (CHF) Hx_CHF	☐ 0 NO	☐ 1 YES
11.	Is a recent Ejection Fraction measurement available? HX_EF	☐ 0 NO	☐ 1 YES
12.	If yes, Ejection Fraction (in percent, most recent) HX_EF%	___ ___ %	
13.	Or, if qualitative: HX_EFqual	☐ 1 30 – 50%	☐ 2 > 50%
14.	Date of most recent EF - month HX_EFdateMM	___ ___	
15.	Date of most recent EF - year HX_EFdateYY	___ ___ ____ ____	
16.	Pulmonary embolism Hx_PE	☐ 0 NO	☐ 1 YES
17.	Deep vein thrombosis (DVT) requiring anti-coagulant Hx_DVT	☐ 0 NO	☐ 1 YES
18.	Ischemic dilated cardiomyopathy Hx_IDC	☐ 0 NO	☐ 1 YES
19.	Moderate to severe mitral or aortic stenosis Hx_aorsten	☐ 0 NO	☐ 1 YES
20.	Moderate to severe mitral regurgitation Hx_mitregurg	☐ 0 NO	☐ 1 YES
21.	Hypertension (Blood pressure ≥ 140/90 or taking anti-hypertension meds) Hx_Hyper	☐ 0 NO	☐ 1 YES
22.	Transient ischemic attack (TIA) Hx_TIA	☐ 0 NO	☐ 1 YES
23.	Stroke Hx_Stroke	☐ 0 NO	☐ 1 YES
24.	Date of most recent Stroke/TIA - month HX_StrokedateMM	___ ___	
25.	Date of most recent Stroke/TIA - year HX_StrokedateYY	___ ___ ____ ____	
26.	What was the etiology of the stroke? HX_StrokeDef	☐ 1 ISCHEMIC	☐ 2 PRIMARY HEMORRHAGIC
27.	Abdominal aortic aneurysm Hx_AAA	☐ 0 NO	☐ 1 YES

AIM-HIGH

MEDICAL HISTORY

SITE ID: _____ _____ PATIENT ID: ___ ___ ___

Patient Initials: ___ ___ ___ ____

28.	Peripheral vascular disease Hx_PVD	☐ 0 NO	☐ 1 YES
29.	Carotid Artery Disease Hx_Carotid	☐ 0 NO	☐ 1 YES
30.	Family history of premature cardiovascular disease Hx_famCVD	☐ 0 NO	☐ 1 YES
*Family history of premature cardiovascular disease is prior to **55 years for male** or **65 years of age for female** 1st degree relative*			
Cardiovascular Interventions			
31.	Coronary artery bypass graft (CABG) Hx_CABG	☐ 0 NO	☐ 1 YES
32.	Date of most recent CABG - month HX_CABGdateMM	___ ___	
33.	Date of most recent CABG - year HX_CABGdat	___ ___ ___ ___	
34.	Percutaneous coronary revascularization (PCI), angioplasty Hx_PCI	☐ 0 NO	☐ 1 YES
35.	Date of most recent - month HX_PCIdateMM	___ ___	
36.	Date of most recent - year HX_PCIdateYY	___ ___ ___ ___	
37.	Was a stent placed? HX_PCIStent	☐ 0 NO	☐ 1 YES
38.	Valve repair/replacement Hx_valve	☐ 0 NO	☐ 1 YES
39.	Abdominal aortic aneurysm repair Hx_AAArepair	☐ 0 NO	☐ 1 YES
40.	Carotid endarterectomy Hx_edart	☐ 0 NO	☐ 1 YES
41.	Carotid Stent Hx_CarotidStent	☐ 0 NO	☐ 1 YES
42.	Peripheral revascularization Hx_PeriRevas	☐ 0 NO	☐ 1 YES
43.	ICD implant Hx_ICD	☐ 0 NO	☐ 1 YES
44.	Pacemaker implant Hx_Pace	☐ 0 NO	☐ 1 YES
Other Medical History			
45.	Chronic pulmonary disease Hx_CPD	☐ 0 NO	☐ 1 YES
46.	Hepatic disease Hx_Hep	☐ 0 NO	☐ 1 YES
47.	Renal disease Hx_Renal	☐ 0 NO	☐ 1 YES
48.	Diabetes mellitus Hx_Diabetes	☐ 0 NO	☐ 1 YES
49.	Year of onset Hx_DiabetesYear	___ ___ ___ ___	
50.	Type Hx_Dtype	☐ 1 TYPE I	☐ 2 TYPE II
51.	Does the current treatment ONLY dietary counseling? Hx_DtreatDiet	☐ 0 NO	☐ 1 YES
52.	Does the current treatment include use of Oral Hypoglycemic? Hx_DtreatOral	☐ 0 NO	☐ 1 YES
53.	Does the current treatment include use of insulin? Hx_DtreatInsulin	☐ 0 NO	☐ 1 YES
54.	Is patient currently using a glucometer? HX_Glucom	☐ 0 NO	☐ 1 YES

AIM-HIGH

PHYSICAL EXAM

SITE ID: _____ _____ PATIENT ID: ___ ___ ___

Patient Initials: ___ ___ ___ ____

INSTRUCTIONS: Please complete at Baseline, annually and at end of study. Table Name: PE

	Visit	☐ BASELINE ☐ 12 MONTH ☐ 24 MONTH ☐ 36 MONTH ☐ 48 MONTH ☐ END OF STUDY
1.	Visit Date *(mm/dd/yyyy)*	___ ___ / ___ ___ / PE_VisDt ___ ___ ___ ___ Use (MM / DD / YYYY)
2-3.	Height (round to nearest in/cm)	PE_Ht ___ ___ ___ ☐1 INCHES ☐2 CENTIMETERS PE_Htunits
3.1	Standard height (derived value)	PE_HtStd ___ ___ ___
4-5.	Weight (round to nearest ld/kg)	PE_Wt ___ ___ ___ ☐1 POUNDS ☐2 KILOGRAMS PE_WtUnits
5.1	Standard weight (derived value)	PE_WtStd ___ ___ ___
5.2	BMI (derived value)	PE_BMI ___ ___ ___
6-7.	Waist circumference (round to nearest in/cm)	PE_waist ___ ___ ___ ☐1 INCHES ☐2 CENTIMETERS PE_WaistUnit
7.1	Standard waist circumference (derived value)	PE WaistStd ___ ___ ___
8-9.	Hip circumference (round to nearest inch/centimeter)	PE_Hip ___ ___ ___ ☐1 INCHES ☐2 CENTIMETERS PE_HipUnits
9.1	Standard hip circumference (derived value)	PE_HipStd ___ ___ ___
10-11.	Sitting Blood Pressure	PE_BPsys ___ ___ / PE_BPdia ___ ___ ___ mmHg

Metabolic syndrome (NCEP)

Confirm metabolic syndrome if there are <u>three</u> or more of the following:

- ✓ *A waistline of 40 inches or more for men and 35 inches or more for women*
- ✓ *A blood pressure of 130/85 mm Hg or higher*
- ✓ *A triglyceride level above 150 mg/dl*
- ✓ *A fasting blood glucose (sugar) level greater than 110 mg/dl*
- ✓ *A high density lipoprotein level (HDL) less than 40 mg/dl (men) or under 50 mg/dl (women)*

12.	Does the patient have Metabolic Syndrome (NCEP) PE_Met	☐0 NO ☐1 YES

Canadian Cardiovascular Class:

I. Ordinary physical activity, such as walking and climbing stairs, does not cause angina. Angina with strenuous or rapid or prolonged exertion at work or recreation.

II. Slight limitations of ordinary activity. Walking or climbing stairs rapidly, walking uphill, walking or stair climbing after meals, or in cold, or in wind, or under emotional stress, or only during the few hours after awakening. Walking more than two blocks on the level and climbing more than one flight of ordinary stairs at a normal pace and in normal conditions.

III. Marked limitation of ordinary physical activity. Walking one to two blocks on the level and climbing more than one flight of stairs in normal conditions and at normal pace.

IV. Inability to carry on any physical activity without discomfort - angina syndrome may be present at rest.

13.	What is the patient's CCS classification at this visit? PE_AnginaDef	☐0 NO ANGINAL SYMPTOMS ☐1 I ☐2 II ☐3 III ☐4 IV

AIM-HIGH

REVASCULARIZATION

SITE ID: _____ _____ PATIENT ID: ___ ___ ___

Patient Initials: ___ ___ ___ ____

INSTRUCTIONS: Fill this form out if the patient has any revascularization procedure.

AIM-HIGH Physician Investigator must review materials to determine whether revascularization was "symptom-driven" or not. See reverse side for definitions.

BE SURE TO SUBMIT ALL DOCUMENTING MATERIALS TO AXIO RESEARCH AS SOON AS POSSIBLE.

Table Name: RV

1.	Date of revascularization procedure RV_Date	___ ___ / ___ ___ / ___ ___ ___ ___ USE (MM / DD / YYYY)
2.	Type of revascularization RV_Type	☐ 1 CARDIAC ☐ 2 CERBROVASCULAR ☐ 3 PERIPHERAL
3.	What type of cardiac procedure? RV_CardType	☐ 1 ANGIOPLASTY WITHOUT STENT ☐ 2 STENT ☐ 3 OTHER PCI (E.G. ATHERECTOMY, ROTATIONAL ABLATION LASER) ☐ 4 CABG
4.	Was the procedure performed as an in-patient procedure? RV_hospital	☐ 0 NO ☐ 1 YES
5.	Date of admission *(mm/dd/yyyy)* RV_adminDt	___ ___ / ___ ___ / ___ ___ ___ ___ USE (MM / DD / YYYY)
6.	Date of discharge *(mm/dd/yyyy)* RV_disDt	___ ___ / ___ ___ / ___ ___ ___ ___ USE (MM / DD / YYYY)
7.	Did an MI occur within 3 days following the procedure? RV_MI	☐ 0 NO ☐ 1 YES
8.	Did AIM-HIGH investigator review materials for this event? RV_Review	☐ 0 NO ☐ 1 YES
9.	Was the procedure "symptom driven"? RV_Symptom	☐ 0 NO ☐ 1 YES ☐ 9 UNABLE TO DETERMINE
Please indicate below what was the basis for determination of "symptom driven".		
10.	Medical records (e.g., admission or discharge notes, operative reports, etc. Include in documentation and send to Coordinating Center) RV_Records	☐ 0 NO ☐ 1 YES
11.	Patient report RV_Report	☐ 0 NO ☐ 1 YES
12.	AIM-HIGH Physician evaluation (summarize in signed narrative and send to Coordinating Center) RV_AHeval	☐ 0 NO ☐ 1 YES
13.	Other physician evaluation (obtain letter or other written documentation from physician to send to Coordinating Center) RV_Oteval	☐ 0 NO ☐ 1 YES

Revascularization is defined as any of the following procedures:

- Coronary revascularization: PCI (includes percutaneous transluminal coronary angioplasty [PTCA], coronary stenting, and others such as brachytherapy, atherectomy, laser, and rotational ablation) or CABG.
- Cerebrovascular revascularization: carotid endarterectomy, carotid percutaneous transluminal angioplasty (with or without stent).
- Peripheral revascularization: peripheral arterial bypass surgery, or any therapeutic intervention for critical leg ischemia (including thrombolysis)
- Renovascular surgery

Symptom driven is defined as:

- Symptoms lead to revascularization regardless of whether or not the procedure itself is successful
- Worsening symptoms after randomization associated with ischemia demonstrated on non-invasive testing or coronary disease progression at angiography followed by PCI or CABG at least 30 days after randomization
- Worsening symptoms after randomization associated with revascularization of the cerebrovascular or peripheral vascular system at least 30 days after randomization
- Persistent stable symptoms after randomization associated with ischemia demonstrated on non-invasive testing or coronary disease progression at angiography followed by PCI or CABG 6 or more months after randomization

Revascularization, not symptom driven is defined as:

- Revascularization procedures for restenosis, early or late stent thrombosis
- Elective coronary revascularization procedures in non-symptom driven patients even if non-invasive testing is abnormal since it cannot be determined if this represents disease that was present before randomization (for example, as part of a non-cardiac preoperative work-up, a non-invasive test reveals ischemia leading to angiography and coronary revascularization)

AIM-HIGH

RUN-IN

SITE ID: _____ _____ PATIENT ID: ___ ___ ___

Patient Initials: ___ ___ ___ ____

Table Name: RunI

INSTRUCTIONS: Fill this form out at completion of run-in, whether or not the patient is to be randomized.

1.	Date Niacin Extended-Release was dispensed.	RunI_StartDt ___ ___ / ___ ___ / ___ ___ ___ ___ USE (MM / DD / YYYY)
2.	How frequently did the patient experience flushing? RunI_Flush	☐ 1 NO FLUSHING REPORTED ☐ 2 INFREQUENTLY (ONLY A FEW TIMES DURING THIS PERIOD) ☐ 3 MODERATELY FREQUENTLY MANY DAYS, BUT NOT EVERY DAY) ☐ 4 DAILY (ALMOST EVERY DAY, USUALLY FOLLOWING THE DOSE)
3.	On average, how severe (annoying) were the flushing episodes?	☐ 0 NO SYMPTOMS ☐ 1 MILD ☐ 2 MODERATE ☐ 3 SEVERE RunI_Flush2
4.	Did the patient take aspirin or other analgesic prior to taking the Niacin Extended-Release?	☐ 0 NO ☐ 1 YES RunI_Prior
5.	Maximum niacin dose tolerated.	☐ 0 NONE TOLERATED ☐ 1 500 MG/DAY ☐ 2 1000 MG/DAY ☐ 3 1500 MG/DAY ☐ 4 2000 MG/DAY RunI_MaxDose
If patient tolerated less than 1,500 mg/day, select the reasons why below.		
6.	Intolerable flushing despite aspirin/NSAID co-therapy	☐ 0 NO ☐ 1 YES RunI_Flush_ASA
7.	Abnormal heart rhythm or heart rate	☐ 0 NO ☐ 1 YES RunI_Arrhythmia
8.	Glycemic control in diabetics	☐ 0 NO ☐ 1 YES RunI_GlycControl
9.	Pruritis (itching)	☐ 0 NO ☐ 1 YES RunI_Itch
10.	Other	☐ 0 NO ☐ 1 YES RunI_OthIntol
11.	Describe other symptoms that made Niacin Extended-Release intolerable.	_____ RunI_Spc_othIntol _____ _____
12.	How many bottles of Zocor (simvastatin) were dispensed during Run-In?	☐ 0 NONE ☐ 1 ONE ☐ 2 TWO RunI_Sim_Disp

Continue 2nd page

RUN-IN

13.	How many bottles of Niacin Extended-Release were dispensed during Run-In?	☐ 1 ONE RunI_Niac_Disp	☐ 2 TWO
14.	Number of Niacin Extended-Release tablets returned.	___ ___ ___ RunI_NiaspanRtn	
15.	Was adherence poor (or suspected as poor)? If yes, select the primary reason. RunI_BadWhy	☐ 0 GOOD COMPLIANCE ☐ 1 ADVERSE CLINICAL SYMPTOMS ☐ 2 PATIENT FORGETFUL ☐ 3 NON-STUDY PHYSICIAN RECOMMENDED DIFFERENT DOSE	☐ 4 PATIENT DECISION ☐ 5 SUPPLY RAN OUT ☐ 6 UNKNOWN ☐ 7 OTHER
16.	If other reason for poor adherence, please describe. RunI_BadSpcWhy	_____ _____ _____	

Confirm whether the patient can be randomized to the study. If the patient CANNOT be randomized to the study, please give the reason why and mark the patient as DISCONTINUED.

If the patient will be randomized, complete and RANDOMIZE using the Web system.

17.	Will patient be randomized to double-blind phase? RunI_Rand	☐ 0 NO	☐ 1 YES
18.	If not, why? RunI_WhyNot	☐ 1 DID NOT TOLERATE AT LEAST 1,500 MG/DAY OF NIACIN EXTENDED-RELEASE ☐ 2 PATIENT REFUSAL ☐ 3 REFERRING PHYSICIAN REFUSAL	☐ 4 PATIENT DIED ☐ 5 EXCLUSION CRITERIA ☐ 6 POOR ADHERENCE ☐ 7 OTHER INTERVENING EVENT
19.	If other intervening event, please specify RunI_SpcWhyNot	_____ _____ _____	

AIM-HIGH

SCREENING & ELIGIBILITY

SITE ID: _____ _____ PATIENT ID: ___ ___ ___

Patient Initials: ___ ___ ___ ____

Table Name: INCL

INSTRUCTIONS: Please complete at the Screening Visit.

INCL_Age	1.	Is the patient at least 45 years old?	☐ 0 NO	☐ 1 YES
Risk Factors:		At least one risk factor (question 2-6) must be documented.		
INCL_CAD	2.	Does the patient have documented multi-vessel CAD (with one or more ≥ 50% stenosis in two major epicardial coronary arteries)?	☐ 0 NO	☐ 1 YES
INCL_MI	3.	Has the patient experienced a documented myocardial infarction?	☐ 0 NO	☐ 1 YES
INCL_ACS	4.	Has the patient been hospitalized for acute coronary syndrome (ACS) with objective evidence of ischemia?	☐ 0 NO	☐ 1 YES
INCL_CVD	5.	Does the patient have documented cerbrovascular or carotid disease?	☐ 0 NO	☐ 1 YES
INCL_PAD	6.	Does the patient have documented symptomatic peripheral artery disease (PAD)?	☐ 0 NO	☐ 1 YES

If the patient meets inclusion criteria 1-6, has signed the screening consent, and has no obvious clinical exclusions, then enter this patient into the eDC system.

Assign an AIM-HIGH ID and obtain screening blood sample.

7.	Was the patient taking a *statin* drug at the time of screening? INCL_OnStatin	☐ 0 NO	☐ 1 YES
8.	If yes, which? INCL_StatinType	☐ 1 Atorvastatin (Lipitor®) ☐ 2 Fluvastatin (Lescol®) ☐ 3 Lovastatin (Altocor® or Mevacor®)	☐ 4 Pravastatin (Pravaco®l) ☐ 5 Rosuvastatin (Crestor®) ☐ 6 Simvastatin (Zocor®) ☐ 7 Other
9	If other, please specify INCL_StatinOth	_____	
10.	What dose level of statin (in mgs) is the patient taking? INCL_StatinDose	____ ____ MGS/DAY	
11.	Is LDL-C in the protocol specified range? INCL_LDL	☐ 0 NO	☐ 1 YES
12.	Is HDL-C in the protocol specified range? INCL_HDL	☐ 0 NO	☐ 1 YES
13.	Are the triglycerides in the protocol specified range? INCL_TG	☐ 0 NO	☐ 1 YES

LDL Level	10 mg		20 mg		40 mg		80 mg	
Statin	mg/dL	mmol/L	mg/dL	mmol/L	mg/dL	mmol/L	mg/dL	mmol/L
None	≤ 160	≤ 4.0	≤ 160	≤ 4.0	≤ 160	≤ 4.0	≤ 160	≤ 4.0
Atorvastatin	≤ 100	≤ 2.6	≤ 90	≤ 2.3	≤ 82	≤ 2.1	≤ 77	≤ 2.0
*Pravastatin**	≤ 125	≤ 3.2	≤ 115	≤ 3.0	≤ 104	≤ 2.7	≤ 98	≤ 2.5
Simvastatin	≤ 115	≤ 3.0	≤ 104	≤ 2.7	≤ 98	≤ 2.5	≤ 86	≤ 2.2
Fluvastatin	--	--	≤ 125	≤ 3.2	≤ 120	≤ 3.1	≤ 102	≤ 2.6

*or *Lovastatin* **for *Rosuvastatin* 5 mg use 100 mg/dL (2.6 mmol/L)

No or ***Off*** Statin Therapy	On Statin Therapy

HDL-C ≤ (men)	40 mg/dl (1.0 mmol)	HDL-C ≤ (men)	42 mg/dl (1.1 mmol)
HDL-C ≤ (women)	50 mg/dl (1.3 mmol)	HDL-C ≤ (women)	53 mg/dl (1.4 mmol)
TG between	150 - 400 mg/dl (1.7-4.5 mmol)	TG between	125 - 400 mg/dl (1.4-4.5 mmol)

AIM-HIGH

SERUM CHEMISTRY

SITE ID: _____ _____ PATIENT ID: ___ ___ ___

Patient Initials: ___ ___ ___ ____

INSTRUCTIONS: Review the Serum Chemistry data from the Central Lab and fill out the form below. Describe if the value for each was clinically significant. If yes, please have the *AIM-HIGH* physician provide a diagnostic comment. If measurement for an analyte was NOT done, please skip the question(s).

Table Name: Scm

	Visit	☐ BASELINE ☐ 1 MONTHS ☐ 3 MONTHS ☐ 6 MONTHS	☐ 12 MONTHS ☐ 18 MONTHS ☐ 24 MONTHS ☐ 30 MONTHS	☐ 36 MONTHS ☐ 42 MONTHS ☐ 48 MONTHS ☐ 54 MONTHS	☐ 60 MONTHS If other visit, ___ ___ Month
1.	Date the blood draw was taken *mm/dd/yyyy)*	___ ___ / ___ ___ / Scm_Date ___ ___ ___ ___ USE (MM / DD / YYYY)			
2.	Had the patient fasted prior to the blood draw?	☐ 0 NO Scm_Fast	☐ 1 YES		
3.	Creatinine Kinase (CK) Scm_CK	☐ 0 NORMAL ☐ 1 ABNORMAL, BUT NOT SIGNIFICANT ☐ 2 LOW, AT CONCERN LEVEL	☐ 3 LOW, AT CLINICAL WARNING LEVEL ☐ 4 HIGH, AT CONCERN LEVEL ☐ 5 HIGH, AT CLINICAL WARNING LEVEL		
4.	If levels are clinically significant, provide comment.	Scm_CK_Cm _____			
5.	Uric Acid Scm_UA	☐ 0 NORMAL ☐ 1 ABNORMAL, BUT NOT SIGNIFICANT ☐ 2 LOW, AT CONCERN LEVEL	☐ 3 LOW, AT CLINICAL WARNING LEVEL ☐ 4 HIGH, AT CONCERN LEVEL ☐ 5 HIGH, AT CLINICAL WARNING LEVEL		
6.	If levels are of clinically significant, please provide comments.	Scm_UA_Cm _____			
7.	HGBA1c Scm_HGBA	☐ 0 NORMAL ☐ 1 ABNORMAL, BUT NOT SIGNIFICANT ☐ 2 LOW, AT CONCERN LEVEL	☐ 3 LOW, AT CLINICAL WARNING LEVEL ☐ 4 HIGH, AT CONCERN LEVEL ☐ 5 HIGH, AT CLINICAL WARNING LEVEL		
8.	If levels are of clinically significant, please provide comments.	Scm_ HGBA _Cm _____			
9.	Glucose Scm_Glu	☐ 0 NORMAL ☐ 1 ABNORMAL, BUT NOT SIGNIFICANT ☐ 2 LOW, AT CONCERN LEVEL	☐ 3 LOW, AT CLINICAL WARNING LEVEL ☐ 4 HIGH, AT CONCERN LEVEL ☐ 5 HIGH, AT CLINICAL WARNING LEVEL		
10.	If levels are of clinically significant, please provide comments.	Scm_Glu _Cm _____			
11.	Aspartate Transaminase (AST) Scm_AST	☐ 0 NORMAL ☐ 1 ABNORMAL, BUT NOT SIGNIFICANT ☐ 2 LOW, AT CONCERN LEVEL	☐ 3 LOW, AT CLINICAL WARNING LEVEL ☐ 4 HIGH, AT CONCERN LEVEL ☐ 5 HIGH, AT CLINICAL WARNING LEVEL		
12.	If levels are of clinically significant, please provide comments.	Scm_AST_Cm _____			

Continue 2nd page

AIM-HIGH

SERUM CHEMISTRY

SITE ID: _____ _____ PATIENT ID: ___ ___ ___

Patient Initials: ___ ___ ___ ____

13.	Creatinine Scm_Cre	☐ 0 NORMAL ☐ 1 ABNORMAL, BUT NOT SIGNIFICANT ☐ 2 LOW, AT CONCERN LEVEL ☐ 3 LOW, AT CLINICAL WARNING LEVEL ☐ 4 HIGH, AT CONCERN LEVEL ☐ 5 HIGH, AT CLINICAL WARNING LEVEL
14.	If levels are of clinically significant, please provide comments.	Scm_Cre_Cm _____
15.	Creatinine Clearance Scm_CC	☐ 0 NORMAL ☐ 1 ABNORMAL, BUT NOT SIGNIFICANT ☐ 2 LOW, AT CONCERN LEVEL ☐ 3 LOW, AT CLINICAL WARNING LEVEL ☐ 4 HIGH, AT CONCERN LEVEL ☐ 5 HIGH, AT CLINICAL WARNING LEVEL
16.	If levels are of clinically significant, please provide comments.	Scm_CC_Cm _____

AIM-HIGH

STUDY TERMINATION

SITE ID: _____ _____ PATIENT ID: ___ ___ ___

Patient Initials: ___ ___ ___ ____

INSTRUCTIONS: Fill this form out at the last study visit for all patients (including early termination)

Table Name: Term

1.	Last Patient Contact Date *(mm/dd/yyyy)*	Term_Date ___ ___ / ___ ___ / ___ ___ ___ ___ Use (MM / DD / YYYY)
2.	What was the primary reason for withdrawal from the study? If death, complete Death Event form and submit documenting materials.	☐ 1 END OF STUDY ☐ 2 PROTOCOL VIOLATION ☐ 3 PATIENT REQUEST ☐ 4 NON-STUDY PHYSICIAN REQUEST ☐ 5 DEATH ☐ 6 LOST TO FOLLOW-UP Term_Reason
3.	Did the patient remain on study drug throughout the trial? If no, make sure that a Drug Dose Adjustment/Discontinuation page documents when study drug was discontinued.	☐ 0 NO ☐ 1 YES Term_Drug
4.	If still alive and withdrawn prior to end of study, did patient agree to allow follow-up through medical records for study endpoints? If yes, obtain consent to request medical records.	☐ 0 NO ☐ 1 YES Term_MedRecs
5.	Will patient remain on lipid lowering/modifying treatments? If yes, which one(s)?	☐ 0 NO ☐ 1 YES Term_LipidTx
6.	Statins	☐ 0 NO ☐ 1 YES Term_Statin
7.	Bile Acid sequestrates	☐ 0 NO ☐ 1 YES Term_BileAcid
8.	Nicotinic acid	☐ 0 NO ☐ 1 YES Term_Nicotin
9.	Fibric acids	☐ 0 NO ☐ 1 YES Term_Fibric
10.	Cholesterol absorption inhibitors	☐ 0 NO ☐ 1 YES Term_Absorb
11.	Other lipid modifying agents	☐ 0 NO ☐ 1 YES Term_OtherDr
12.	Therapeutic lifestyle changes (diet & exercise) ONLY	☐ 0 NO ☐ 1 YES Term_TLC

SITE ID: _____ _____ PATIENT ID: ___ ___ ___

Patient Initials: ___ ___ ___ ____

SUSPECTED TOXICITY

Table Name: TOX

INSTRUCTIONS: Add a row to the form each time drug toxicity is suspected.

1.	Date evaluated (mm/dd/yyyy) Tox_Dt	___ ___ / ___ ___ / ___ ___ ___ ___ Use (MM / DD / YYYY)
2.	What is the reason for completion? Tox_Lab	☐ 1 HEPATOTOXICITY ☐ 2 MYOPATHY ☐ 3 LOW LDL
3.	Most recent CK level (in U/L)	Tox_CK ___ ___ ___
4.	Most recent AST level (in U/L)	Tox_AST ___ ___ ___
5.	Most recent ALT level (in U/L)	Tox_ALT ___ ___ ___
6.	Did the patient experience fatigue? (If yes, note severity) Tox_Fatigue	☐ 0 NO SYMPTOMS ☐ 2 MODERATE ☐ 1 MILD ☐ 3 SEVERE
7.	Did patient report muscle aches or weakness? (If yes, note severity) Tox_MAches	☐ 0 NO SYMPTOMS ☐ 2 MODERATE ☐ 1 MILD ☐ 3 SEVERE
8.	Did patient report diarrhea? (If yes, note severity) Tox_Diarrhea	☐ 0 NO SYMPTOMS ☐ 2 MODERATE ☐ 1 MILD ☐ 3 SEVERE
9.	Did the patient experience nausea or vomiting? (If yes, note severity) Tox_Nausea	☐ 0 NO SYMPTOMS ☐ 2 MODERATE ☐ 1 MILD ☐ 3 SEVERE
10	Did the patient report any marked changes in urine? (If yes, note severity) Tox_Urine	☐ 0 NO SYMPTOMS ☐ 2 MODERATE ☐ 1 MILD ☐ 3 SEVERE
11.	Did the patient show signs of jaundice? (If yes, note severity) Tox_jaundice	☐ 0 NO SYMPTOMS ☐ 2 MODERATE ☐ 1 MILD ☐ 3 SEVERE