Date Entered_____
Initials_____

BARI 2D ANGIOGRAPHIC ACQUISITION FORM

BARI 2D ID__ __ __ __ __ __ __ __ __ __ __

---

1. Categorize procedure: **(Check only one)**

Angiogram at Baseline without PCI	1( )
Angiogram at Baseline with PCI	2( )
Assigned BARI 2D initial PCI	3( )

2. Is angiogram available to be sent to the Core Lab?

No 0( ) → 2.1 Specify reason not available: _____

Yes 1( )

3. Date of Angiogram: ____/___/____
mm dd yyyy

4. Time of Angiogram: _____:_____(use military time)
hh mm

5. Record media:

CD 1( ) ***(be sure to include LV angio, cors/grafts and PCI on CD, if applicable)***

Cine film 2( )

6. Record catheter size:

6.1 Diagnostic (Circle applicable size):	5	6	7	8	9
6.2 PCI (Circle applicable size):	6	7	8	9	10

7. Was nitroglycerin given in any form prior to/during the procedure?
(this includes oral, sublingual, intravenous, intracoronary, and transcutaneous nitroglycerin)

No 0( )

Yes 1( )

Label CD or cine film (and accompanying box or jewel case) with date and BARI 2D ID

Mail angiogram and this form via express mail using preprinted labels to:

Attention: Anne Schwarzkopf
BARI 2D Core Angiographic Laboratory
300 Pasteur Dr., Room H2170
Stanford, CA 94305
Phone (650) 723-1866

……

Name code of person completing form ___ ___ ___ ___ ___
Date of form completion____/____/_____
mm dd yyyy

BARI 2D ANNUAL BRIEF FOLLOW-UP FORM

Date Entered_____
Initials_____

Date Verified_____
Initials_____

BARI 2D ID__ __ __ __ __ __ __ __ __ __ __

Patient Name_____

COMPLETE ONLY FOR PATIENTS WITH AN INACTIVATED BARI 2D ID WHO HAVE AGREED TO ANNUAL BRIEF FOLLOW-UP

---

1. Date of evaluation: ____/____/____
mm dd yyyy

2. Indicate follow-up period:

1 year	1( )
2 years	2( )
3 years	3( )
4 years	4( )
5 years	5( )
6 years	6( )

3. Did the patient die since the last contact?

No 0( )
Yes 1( ) ⟶

3.1 Date of death: ____/____/____
mm dd yyyy

3.2 Will additional death information be available?
No 0( )
Yes 1( )

4. Is there any reason to suspect an MI has occurred since the last contact?

No 0( )
Yes 1( ) ⟶

4.1 Record number of MIs: _____

4.2 Record the date(s) of the MI(s):
4.2.1 ____/____
4.2.2 ____/____
mm yyyy

5. Has the patient had a cardiac revascularization procedure since the last contact?

No 0( )
Yes 1( ) →

5.1 PCI Procedure:
No 0 ( )
Yes 1 ( ) →
5.1.1 Record number of PCI procedures: _____
5.1.2 Record the date(s) of the PCI(s):
5.1.2.1 ____/____
5.1.2.2 ____/____
mm yyyy

5.2 CABG:
No 0 ( )
Yes 1 ( ) →
5.2.1 Record number of CABG surgeries: _____
5.2.2 Record the date(s) of the surgery:
5.2.2.1 ____/____
5.2.2.2 ____/____
mm yyyy

6. Has the patient experienced ischemic chest pain since last contact?

No 0( )
Yes 1( ) →

6.1 Categorize angina:
(Check only one)

Stable 1( ) →
6.1.1 Record Canadian Cardiovascular Society Classification:
I( ) II( ) III( ) IV( )

Unstable 2( )

Ischemic pain only in association with acute MI 3( )

7. Has the patient experienced anginal equivalents or atypical angina since last contact?

No 0( )
Yes 1( ) →

Record symptoms experienced:

	No	Yes
7.1 Shortness of breath	0( )	1( )
7.2 Dyspnea on exertion	0( )	1( )
7.3 Exertional fatigue	0( )	1( )
7.4 Nausea	0( )	1( )
7.5 Unexplained diaphoresis	0( )	1( )
7.6 Other	0( )	1( )

Specify: _____

8. Has the patient had a cerebrovascular accident (stroke) since the last contact?

No 0( )
Yes 1( ) →

8.1 Record number of strokes: _____

8.2 Record the date(s) of the stroke(s):
8.2.1 ____/____
8.2.2 ____/____
mm yyyy

……

Name code of person completing form ___ ___ ___ ___ ___

Date of form completion____/____/_____
mm dd yyyy

CANADIAN CARDIOVASCULAR SOCIETY CLASSIFICATION

Class	Definition
I	Ordinary physical activity, such as walking and climbing stairs, does not cause angina. Angina with strenuous rapid or prolonged exertion at work or recreation.
II	Slight limitation of ordinary activity. Walking or climbing stairs rapidly, walking uphill, walking or stair climbing after meals, in cold, in wind, or when under emotional stress or during the first few hours after awakening may cause pain. Walking more than two blocks on the level and climbing more than one flight of ordinary stairs at a normal pace and in normal pace and in normal conditions.
III	Marked limitation of ordinary physical activity. Walking 1-2 blocks on a level and climbing one flight at normal conditions results in angina.
IV	Inability to carry on any physical activity without discomfort. Anginal syndrome may be present at rest.

Date Entered_____
Initials_____

Date Verified_____
Initials

BARI 2D CLINIC VISIT MONITORING FORM

BARI 2D ID__ __ __ __ __ __ __ __ __ __ __

Patient Name_____

DO NOT COMPLETE SHADED QUESTIONS FOR BASELINE VISIT

SECTION A: FOLLOW-UP INFORMATION

1. Date of Visit: ____/____/____
   mm dd yyyy
   For Baseline, this date should reflect the date of the one week diabetology visit when Randomized Treatment is begun.

2. Follow-up Period:

Year 0 ( ) → Month: Baseline 0 ( )
1 ( ) 1 ( )
2 ( ) 2 ( )
3 ( ) 3 ( )
4 ( ) 4 ( )
5 ( ) 5 ( )
6 ( ) 6 ( )
7 ( ) 9 ( )

Quarter 1 ( )
2 ( )
3 ( )
4 ( )

Unscheduled U( ) → Reason for unscheduled visit_____

3. Did the clinic visit occur at a BARI 2D facility (i.e. primary or satellite site)?
   No 0( )
   Yes 1( )

4. Did BARI 2D personnel conduct the visit?
   No 0( )
   Yes 1( )

SECTION B: ENDPOINTS

1. Did the patient die since the last clinic visit or since randomization (if this is the Baseline Visit)?
   No 0( )
   Yes 1( ) → Complete Mortality Checklist (DC)

2. Is there any reason to suspect an MI has occurred since the last clinic visit or since randomization (if this is the Baseline Visit)?
   No 0( )
   Yes 1( ) → Complete Suspected MI Checklist (MIL)

SECTION B: ENDPOINTS

3. Did the patient have a cerebrovascular accident (stroke) since the last clinic visit or since randomization (if this is the Baseline Visit)?

No 0( )
Yes 1( ) → Complete Cerebrovascular Accident Form (CVA)

4. Has the patient had a cardiac revascularization procedure since the last clinic visit or since randomization (if this is the Baseline Visit)? Include any revascularizations performed on the date of the current clinic visit.

No 0( )
Yes 1( ) →

4.1 PCI Procedure:
No 0 ( )
Yes 1 ( ) → Complete PCI Procedure Form (PP)
4.1.1 Record number of procedures _____

4.2 CABG:
No 0 ( )
Yes 1 ( ) → Complete Surgery Procedure Form (SP)
4.2.1 Record number of procedures _____

4.3 Laser Myocardial Revascularization:
No 0 ( )
Yes 1 ( ) → 4.3.1 Date of Procedure: _____/_____/_____ mm dd yyyy

5. Has the patient been HOSPITALIZED (including other hospitals) for any reason since the last clinic visit or since randomization (if this is the Baseline Visit)?

No 0( )
Yes 1( ) →
5.1 Number of hospital admissions_____
5.2 Estimated total number of days hospitalized_____

SECTION C: HISTORY / PHYSICAL EXAM

1. Record weight: _____ kg

2. Has the patient gained or lost weight since last visit? (≥ 2.5 kg for 1 month visit OR ≥ 5 kg for 3 month visit)

No 0( )
Lost weight 1( )
Gained weight 2( ) →

Reason for weight change in opinion of clinician:

	No	Yes
2.1 Caloric imbalance	0 ( )	1( )
2.2 Fluid retention or loss	0 ( )	1( )
2.3 Uncertain	0 ( )	1( )

SECTION C: HISTORY / PHYSICAL EXAM

3. Has the patient experienced ischemic chest pain since last clinic visit?

No 0( )
Yes 1( ) →

3.1 Categorize angina:
(Check only one)

Stable 1( ) → 3.1.1 Record Canadian Cardiovascular Society Classification: I( ) II( ) III( ) IV( )
Unstable 2( )
Ischemic pain only in association with acute MI 3( )

4. Has the patient experienced anginal equivalents or atypical angina since last clinic visit?

No 0( )
Yes 1( ) →

Record symptoms experienced:

	No	Yes
4.1 Shortness of breath	0( )	1( )
4.2 Dyspnea on exertion	0( )	1( )
4.3 Exertional fatigue	0( )	1( )
4.4 Nausea	0( )	1( )
4.5 Unexplained diaphoresis	0( )	1( )
4.6 Other	0( )	1( )

Specify: _____

5. Does the patient have peripheral pitting edema 1+ or greater?

No 0( )
Yes 1( ) →

5.1 Record greatest extent of edema:

Pedal	1( )
Ankle	2( )
Calf	3( )
Thigh	4( )
Upper extremity	5( )

SECTION C: HISTORY / PHYSICAL EXAM

6. Does the patient have rales?

No 0( )
Yes 1( ) →

Record location:

	No	Yes	Base	½	¾	Full
6.1 Right	0( )	1( ) →	1( )	2( )	3( )	4( )
6.2 Left	0( )	1( ) →	1( )	2( )	3( )	4( )

7. Sitting Blood Pressure:

7.1 Specify arm used for measurement:

Right 1( )

Left 2( )

7.2 Systolic Blood Pressure _____mmHg

7.3 Diastolic Blood Pressure _____ mmHg

8. 30-second pulse _____ beats

9. Is blood pressure > 130 systolic or > 80 diastolic?

No 0( )
Yes 1( ) →

9.1 Is action required based on clinician judgment?

No 0 ( )
Yes 1 ( ) →

Action taken:

	No	Yes
9.1.1 Dietary counseling	0( )	1( )
9.1.2 Medication change	0( )	1( )
9.1.3 Other	0( )	1( )

Specify:_____

10. Was serum potassium level obtained since the last clinic visit?

No 0( )
Yes 1( ) →

10.1 Record value: _____mEq/L _____ mmol/L

11. Was serum creatinine level obtained since the last clinic visit?

No 0( )
Yes 1( ) →

11.1 Record value: _____mg/dl _____ µmol/L

SECTION C: HISTORY / PHYSICAL EXAM

12. Has the patient experienced congestive heart failure (CHF) since the last evaluation?
No 0( )
Yes 1( ) →

12.1 Has the patient been on a combination of insulin plus thiazolidinedione since the last evaluation?
No 0( )
Yes 1( )

12.2 Which CHF symptoms did the patient have?
(Check all that apply)

12.2.1 Orthopnea
No 0( )
Yes 1( ) →
12.2.1.1 Did the symptoms occur after combination therapy was initiated?
No 0( )
Yes 1( )
N/A (Answered "No" to question 12.1) -2( )

12.2.2 Paroxysmal nocturnal dyspnea
No 0( )
Yes 1( ) →
12.2.2.1 Did the symptoms occur after combination therapy was initiated?
No 0( )
Yes 1( )
N/A (Answered "No" to question 12.1) -2( )

12.2.3 Dyspnea on exertion
No 0( )
Yes 1( ) →
12.2.3.1 Did the symptoms occur after combination therapy was initiated?
No 0( )
Yes 1( )
N/A (Answered "No" to question 12.1) -2( )

12.2.4 Edema
No 0( )
Yes 1( ) →
12.2.4.1 Did the symptoms occur after combination therapy was initiated?
No 0( )
Yes 1( )
N/A (Answered "No" to question 12.1) -2( )

<u>If any of the CHF symptoms in 12.2 were present, a physical exam should be done to assess the signs below.</u>

12.3 Was a physical exam done?
No 0( )
Yes 1( ) →
Indicate which of the following signs were present during the exam:
12.3.1 Hepatomegaly No 0( ) Yes 1( )
12.3.2 Venous jugular distention No 0( ) Yes 1( )
12.3.3 Pulmonary congestion No 0( ) Yes 1( )
12.3.4 S3 gallop on auscultation of the heart No 0( ) Yes 1( )

SECTION C: HISTORY / PHYSICAL EXAM

13. Was resting LV function assessed since the last clinic visit or since randomization (if this is the Baseline Visit)?

No 0( )

Yes 1( ) →

13.1 Record test performed:

Cardiac Catheterization	1( )
Echo Cardiography	2( )
Nuclear Perfusion Scan	3( )
MRI Cardiac Scan	4( )

13.2 Record calculated resting LV ejection fraction_____ %

13.3 If not calculated, in the opinion of the clinician is the LVEF < 50%?

No 0( )
Yes 1( )

13.4 Was there evidence of diastolic dysfunction on imaging?

No 0( )
Yes 1( ) →
Not assessed 2( )

13.4.1 Stage of diastolic dysfunction (**check one**):

Stage I	1( )
Stage II	2( )
Stage III	3( )
Stage IV	4( )

14. Was B-Type Natriuretic Peptide (BNP) or NT-proBNP measured since last clinic visit?

No 0( )

Yes 1( ) →

14.1 Type of Test Measured **(check one)**:

14.1.1 BNP 1( )

14.1.2 NT-proBNP 2( )

14.2 Record Highest Value : _____pg/mL OR _____pmol/L
(if more than one value available)

14.3 Upper Limit of Normal: _____pg/mL OR _____pmol/L

14.4 Date drawn: _____/_____/_____
mm dd yyyy

SECTION D: GLUCOSE CONTROL

1. Has HbA1c been obtained since the last clinic visit?

No 0 ( )
Yes 1 ( ) →

1.1 Record value (most recent): _____%
1.2 Date of blood draw (most recent): ____ / ____ / ____
mm dd yyyy

2. Is most recent HbA1c ≥7.0% ?

No 0 ( )
Yes 1 ( ) →

2.1 Is action required since the last clinic visit based on clinician judgment?

No 0 ( )
Yes 1 ( ) →

Action taken:	No	Yes
2.1.1 Medication change	0( )	1( )
2.1.2 Dose increase	0( )	1( )
2.1.3 Nutrition counseling	0( )	1( )
2.1.4 Other	0( )	1( )

Specify:_____

3. Was ALT obtained during this visit or in the last 90 days for Baseline Visit?

No 0( )
Yes 1( ) →

3.1 Record date: ____/____/____
mm dd yyyy

3.2 Is ALT more than 3x upper limit of normal?

No 0( )
Yes 1( ) → 3.2.1 Action taken _____

4. Was CK (CPK) obtained during this visit or in the last 90 days for Baseline Visit?

No 0( )
Yes 1( ) →

4.1 Record date: ____/____/____
mm dd yyyy

4.2 Is CK (CPK) more than 10x upper limit of normal?

No 0( )
Yes 1( ) → 4.2.1 Action taken _____

5. THIS QUESTION HAS BEEN DELETED.

SECTION D: GLUCOSE CONTROL

When completing the following section for Baseline indicate if the patient has <u>ever</u> had the complication listed.

6. Since the last evaluation, has the patient had any hypoglycemia episodes?

No 0 ( )

Yes 1 ( ) →

6.1 How often are the hypoglycemia episodes?

Less than once a month	1( )
Once per month	2( )
More than once per month, but not weekly	3( )
Once per week	4( )
2-4 times a week	5( )
Daily	6( )

6.2 Did any hypoglycemia episodes require assistance of another person?

No 0( )

Yes 1( ) → 6.2.1 Number of episodes _____

6.3 Did any hypoglycemia episodes require EMS/ER visit or admission to a hospital?

No 0( )

Yes 1( ) → 6.3.1 Number of episodes _____

6.4 Did any hypoglycemia episode result in coma or convulsions?

No 0( )

Yes 1( ) → 6.4.1 Number of episodes _____

6.5 Were any hypoglycemia episodes associated with:

	No	Yes	Unknown
6.5.1 Recent changes in diabetes medications or doses	0( )	1( )	-3( )
6.5.2 Missed meal or snack	0( )	1( )	-3( )
6.5.3 Exercise	0( )	1( )	-3( )
6.5.4 Alcohol use	0( )	1( )	-3( )
6.5.5 Change in Beta Blocker or increased dose	0( )	1( )	-3( )
6.5.6 Medication Dosage Error	0( )	1( )	-3( )

6.6 Severe hypoglycemia episodes (refer to definition below):

6.6.1 Enter number since last follow-up _____

→ Complete Severe Hypoglycemia Form (SH) for each episode

6.6.2 Enter dates: ___/___/___, ___/___/___, ___/___/___, ___/___/___,

___/___/___, ___/___/___, ___/___/___, ___/___/___

* SEVERE HYPOGLYCEMIA EPISODE:

An event characterized by patient's inability to self-treat and one of the following two conditions: (i) blood glucose <50 mg/dl determined in a health care facility or a finger stick reading determined by non-medical or EMS personnel, or (ii) confusion, irrational or uncontrollable behavior, convulsions, or coma reversed by treatment that raises blood glucose.

SECTION D: GLUCOSE CONTROL

7. Since the last evaluation, has the patient had diabetic ketoacidosis?

No	0( )
Yes	1( )
Unknown	-3( )

8. Since the last evaluation, has the patient had hyperosmolar hyperglycemic nonketotic coma?

No	0( )
Yes	1( )
Unknown	-3( )

9. Since the last evaluation, has the patient had laser treatments for diabetic retinopathy/macular edema?

No	0( )
Yes	1( )

10. Since the last evaluation, has the patient been diagnosed as legally blind due to diabetes?

No	0( )
Yes	1( )

11. Since the last evaluation, has the patient required dialysis?

No	0( )
Yes	1( ) →

11.1 Is renal disease due to diabetes?

No	0( )
Yes	1( )
Etiology unknown	-3( )

12. Since the last evaluation, has the patient had an organ transplant?

No	0( )
Yes	1( ) →

Please specify:

	No	Yes
12.1 Heart	0( )	1( )
12.2 Kidney	0( )	1( )
12.3 Liver	0( )	1( )
12.4 Pancreas	0( )	1( )
12.5 Other	0( )	1( )

Specify:_____

SECTION D: GLUCOSE CONTROL

13. Since the last evaluation, has the patient had a transient ischemic attack?

No 0 ( )
Yes 1 ( )

14. Since the last evaluation, has the patient been hospitalized for lower extremity arterial revascularization?

No 0( )
Yes 1( )

15. Since the last evaluation, has the patient had any lower extremity amputations?

No 0( )
Yes 1( ) ⟶

15.1 Specify site of amputation:

		No	Yes ⟶	Record location: Toe(s)	Ankle or below	Below Knee	Above Knee
15.1.1	Right	0( )	1( )	( )	( )	( )	( )
15.1.2	Left	0( )	1( )	( )	( )	( )	( )

15.2 Was amputation due to diabetes complication?

No 0( )
Yes 1( )

16. Since the last evaluation, has the patient received treatment for lower extremity ulcer?

No 0( )
Yes 1( ) ⟶

16.1 Did treatment require hospitalization?

No 0( )
Yes 1( )

17. Since the last evaluation, has the patient experienced erectile dysfunction (consistent symptoms for at least three months; refer to instructions for a full definition)? ***Answer this question for Baseline and Annual visits only.***

No 0( )
Yes 1( )
N/A -2( )

SECTION E: LIPIDS

1. Has LDL cholesterol been obtained since the last clinic visit?

No 0 ( )
Yes 1 ( ) →

1.1 Record value (most recent): _____ mg/dl _____ mmo1/L
1.2 Date of blood draw (most recent): ____ / ____ / ____
mm dd yyyy

2. Is most recent LDL ≥ 100 mg/dl (2.59 mmol/L)?

No 0( )
Yes 1( ) →

2.1 Is action required based on clinician judgement?

No 0( ) →

Reason(s) for no action:

	No	Yes
2.1.1 Awaiting confirmation of lab value	0( )	1( )
2.1.2 Awaiting glycemic improvement	0( )	1( )
2.1.3 Awaiting improvement of diet	0( )	1( )
2.1.4 Awaiting effect of medication	0( )	1( )
2.1.5 LDL not too high	0( )	1( )
2.1.6 Other	0( )	1( )

Specify: _____

Yes 1( ) →

Action(s) taken:

	No	Yes
2.1.7 Dietary counseling	0( )	1( )
2.1.8 Initiate medication	0( )	1( )
2.1.9 Increase medication	0( )	1( )
2.1.10 Other	0( )	1( )

Specify: _____

SCHEDULE FASTING LIPID PROFILE FOR NEXT QUARTERLY VISIT.
Notes (e.g., no action taken, why?):

_____

_____

_____

SECTION E: LIPIDS

3. Have fasting triglycerides been obtained since the last clinic visit?

No 0 ( )

Yes 1 ( ) →

3.1 Record value (most recent): _____ mg/dl _____ mmo1/L

3.2 Date of blood draw (most recent): ____ / ____ / ____
mm dd yyyy

3.3 How long was patient NOP (except water) prior to specimen being drawn?_____hrs

4. Are the most recent fasting triglycerides ≥ 400 mg/dl (4.52 mmol/L)?

No 0 ( )

4.1 Are the most recent fasting triglycerides ≥ 200 mg/dl (2.26 mmol/L)?

No 0 ( )

Yes 1 ( ) →

Yes 1 ( ) →

4.1.1 Is action required based on clinician judgment?

No 0 ( ) →

Reason(s) for no action:

		No	Yes	N/A
4.1.1.1	Awaiting confirmation of lab value	0( )	1( )	
4.1.1.2	Awaiting glycemic improvement	0( )	1( )	
4.1.1.3	Awaiting diet improvement	0( )	1( )	
4.1.1.4	Clinician considers range 200-400 mg/dl (2.26-4.52 mmol/L) to be acceptable	0( )	1( )	-2( )
4.1.1.5	Other	0( )	1( )	
	Specify:_____			

Yes 1 ( ) →

Action(s) taken:

		No	Yes
4.1.1.6	Dietary counseling	0( )	1( )
4.1.1.7	Initiate Fibrate	0( )	1( )
4.1.1.8	Increase Fibrate	0( )	1( )
4.1.1.9	Initiate Fish oil	0( )	1( )
4.1.1.10	Increase Fish oil	0( )	1( )
4.1.1.11	Other	0( )	1( )
	Specify:_____		

SCHEDULE FASTING LIPID PROFILE FOR NEXT QUARTERLY VISIT.

Notes (e.g., no action taken, why?):

_____

_____

_____

SECTION F: MEDICATIONS

1. Is the patient currently taking insulin?

No 0( )
Yes 1( ) ⟶

Summarize patient's current usual insulin regimen.
(Refer to the most recent day that you would consider typical. Round off to the nearest whole unit.)

1.1 Total number of prolonged acting insulin units per day _____
1.1.1 Record drug code(s)* _____, _____

1.2 Total number of short acting insulin units per day _____
1.2.1 Record drug code(s)* _____, _____

1.3 Is the patient currently using an insulin pump?

No 0( )
Yes 1( ) ⟶

1.3.1 Record drug code of type of insulin used in pump: _____

1.3.2 Record basal dose:
_____units/day

1.3.3 Record typical bolus doses:
_____ units/day

SECTION F: MEDICATIONS

2. Record current medications as of end of clinic visit:
For Baseline Time Point, should reflect beginning of Randomized Diabetes Treatment.

	No	Yes	Drug Code	Total Daily Dose
2.1 Biguanide*	0( )	1( )	_____	_____mg
2.2 Thiazolidinedione**	0( )	1( )	_____	_____mg
2.3 Sulfonylurea	0( )	1( )	_____	_____mg
2.4 Meglitinide	0( )	1( )	_____	_____mg
2.5 Phenylalanine Derivative	0( )	1( )	_____	_____mg
2.6 Alpha Glucosidase Inhibitor	0( )	1( )	_____	_____mg
2.7 HMG-CoA Reductase Inhibitor**	0( )	1( )	_____	_____mg
2.8 Fibrate**	0( )	1( )	_____	_____mg
2.9 Niacin**	0( )	1( )	_____	_____mg
2.10 Bile Acid Sequestrant	0( )	1( )	_____	_____gm
2.11 Omega-3 Fatty Acid	0( )	1( )	_____	_____gm
2.12 Lipase Inhibitor	0( )	1( )	_____	_____mg
2.13 Prolonged Acting Insulin***	0( )	1( )	_____	_____units
			_____	_____units
2.14 Short Acting Insulin***	0( )	1( )	_____	_____units
			_____	_____units
2.15 Insulin Pump	0( )	1( )	_____	_____units
2.16 Steroids	0( )	1( )	_____	_____mg
			_____	_____mg
2.17 Cholesterol Absorption Inhibitor	0( )	1( )	_____	_____mg

*** If patient is taking Biguanide, then serum creatinine should be monitored according to protocol.**

**** If patient is taking these drugs, then liver function test(s) should be monitored according to protocol.**

***** Prolonged Acting Insulin should include: NPH, Lente, Ultralente, Glargine and pre-mixed insulin (e.g. 75/25, 70/30, 50/50).**

Short Acting Insulin should include: Regular, Lispro, and Aspart.

SECTION F: MEDICATIONS

3. Record diabetes treatment assignment to which patient was randomized:

Insulin Providing (IP) 1( ) →

3.1 As of the end of this visit*, is the patient being prescribed an IS drug (i.e., biguanide or thiazolidinedione)?

No 0( ) Yes 1( ) → Answer Questions 3.3-3.7

Insulin Sensitizing (IS) 2( ) →

3.2 As of the end of this visit*, is the patient being prescribed an IP drug (i.e., sulfonylurea, meglitinide, phenylalanine derivative, insulin)?

No 0( ) Yes 1( ) → Answer Questions 3.3-3.7

Reasons/circumstances that explain the use of a diabetes drug from the opposite treatment arm: (Check all that apply)

	No	Yes
3.3 Patient refusing assigned treatment medication	0( )	1( )
3.4 Safety concerns interfering with the prescription of assigned treatment medication	0( )	1( ) →

Indicate which drug classes from assigned treatment arm are **NOT** being prescribed (either at maximum dosages, or at all) due to safety concerns, and for each drug class indicate the specific safety concern:

Drug class[1]	Specific safety concern:
3.4.1 ___	_____
3.4.2 ___	_____
3.4.3 ___	_____

[1] Use 1-letter code: **For IP patients**, use **S** (ulfonylureas), **I** (nsulin), **M** (eglitinide), and **P** (henylalanine derivative).
For IS patients, use **B** (iguanide) and **T** (hiazolidinedione)

3.5 Weaning off opposite treatment drug still in progress	0( )	1( )
3.6 Glycemic goals not reached with the medications from the assigned treatment arm, prescribed at maximum dosages	0( )	1( )
3.7 Other	0( )	1( )

Specify: _____

3.8 Explanations/Clarifications (optional)

_____
_____
_____
_____
_____

*i.e., diabetes regimen documented on Section F, Question 2

SECTION F: MEDICATIONS

4. Record the following cardiac medications taken as of end of clinic visit:

ANTIANGINA/ ANTIHYPERTENSIVE/ HEART FAILURE

		No	Yes	Drug Code	Total Daily Dose
4.1	Beta Blocker	0( )	1( )	_____	_____mg
4.2	Calcium Channel Blocker (verapamil, diltiazem)	0( )	1( )	_____	_____mg
4.3	Calcium Channel Blocker (all others)	0( )	1( )	_____	_____mg
4.4	ACE Inhibitor	0( )	1( )	_____	_____mg
4.5	Angiotensin Receptor Blocker	0( )	1( )	_____	_____mg
4.6	Alpha Blocker	0( )	1( )	_____	_____mg
4.7	Nonsublingual Nitrate	0( )	1( )		
4.8	Sublingual Nitrates or Nitro spray	0( )	1( )		
4.9	IV Nitroglycerin	0( )	1( )		
4.10	Antiarrhythmic agent	0( )	1( )		
4.11	Diuretic	0( )	1( )	_____	_____mg
				_____	_____mg
4.12	Vasodilator (other than the above)	0( )	1( )		
4.13	Digitalis or derivative	0( )	1( )		
4.14	Inotropic agent	0( )	1( )		
4.15	Aldosterone Receptor Antagonist	0( )	1( )	_____	_____mg

ANTIPLATELET/ANTICOAGULANT

4.16	Aspirin	0( )	1( )		
4.17	Ticlopidine/Clopidogrel	0( )	1( )		
4.18	Antiplatelet agent other than ticlopidine, clopidogrel (includes persantine/sulfinpyrazone)	0( )	1( )		
4.19	Heparin (includes low molecular weight heparin)	0( )	1( )		
4.20	Warfarin	0( )	1( )		
4.21	Thrombolytic therapy	0( )	1( )		
4.22	IIb/IIIa receptor antagonist	0( )	1( )		

5. Record other known diabetes or cardiac medications taken as of end of clinic visit:

		No	Yes	Drug Code	Total Daily Dose
5.1	Other Drug Class	0( )	1( )	_____	_____
				_____	_____

6. Does patient currently take antioxidants?

No 0( )

Yes 1( )

7. As of the end of this clinic visit, is the patient being prescribed any of the following combinations?

	No	Yes
7.1 Avandia and Insulin	0( )	1( )
7.2 Avandamet and Insulin	0( )	1( )

8. In the clinician's opinion, has the patient been taking his/her medications as prescribed since the last clinic visit?

Very adherent 1( )

Somewhat adherent 2( )

Not at all adherent 3( )

9. Does the patient have any new contraindication(s) to any diabetes, cardiovascular, antihypertensive or antihyperlipidemia medications?

(*For baseline time point, indicate drugs that are contraindicated at baseline*)

No 0( )

Yes 1( ) ⟶

9.1 Document Drug code(s):
_____ , _____, _____, _____

10. Has the patient suffered from GI intolerance to metformin since the last clinic visit or since completion of the GI Intolerance to Metformin Retrospective Survey (whichever occurred last)?

IP patient (not applicable)	-2 ( )
No	0 ( )
Yes	1 ( )
IS patient has not been on metformin	2 ( )

10.1 Specific manifestation: (**Check all that apply**)	No	Yes
10.1.1 Abdominal pain/stomachache/cramps	0( )	1( )
10.1.2 Nausea/vomiting	0( )	1( )
10.1.3 Diarrhea	0( )	1( )
10.1.4 Gastroparesis	0( )	1( )
10.1.5 Anorexia/loss of appetite	0( )	1( )
10.1.6 Other	0( )	1( )
Specify:_____		

10.2 Impact of GI intolerance with regard to metformin use: (**Check only one**)

Prevents patient from taking metformin	1( )
Allows patient to take metformin but limits dosage	2( )
No impact on metformin use	3( )

SECTION G: LIFESTYLE BALANCE WEIGHT CONTROL PROGRAM

1. Has the patient received the Lifestyle Balance Weight Control Program as part of this clinic visit?

No	0( )
Yes	1( )

2. Has the patient received Lifestyle Balance Weight Control Program counseling as part of this clinic visit?

No	0( )
Yes	1( )

……

Name code of person completing form ___ ___ ___ ___ ___

Date of form completion ____/_____/____
mm dd yyyy

CEREBROVASCULAR ACCIDENT (STROKE): Cerebrovascular accident (stroke) is defined as the rapid onset of a persistent neurologic deficit attributed to an obstruction or rupture of the brain arterial system. The deficit is not known to be secondary to brain trauma, tumor, infection or other cause. The deficit must last more than 24 hours unless death supervenes or there is demonstrable lesion on CT or MRI compatible with an acute stroke.

Diagnosis will be made based on the hospitalization record demonstrating that a stroke has occurred. Strokes will include those events occurring during surgery or procedures and those aborted by thrombolytic therapy.

The definition of stroke excludes old stroke by CT or MRI scans. This is usually diagnosed if the location of the infarct is inappropriate to explain the finding or when there is nearby focal ventricular enlargement. Recent strokes often have edema or show distortion of the brain, are enhancable, or show progression between CT or MRI scans.

STABLE ANGINA: is a pattern of angina that is predictably brought on by the activities the patient engages in. It is promptly relieved by sublingual nitroglycerin or prevented by nitroglycerin and other antianginal medication. The frequency and severity of episodes are similar from day to day.

CANADIAN CARDIOVASCULAR SOCIETY CLASSIFICATION

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

II Slight limitation of ordinary activity. Walking or climbing stairs rapidly, walking uphill, walking or stair climbing after meals, in cold, in wind, or when under emotional stress or during the first few hours after awakening may cause pain. 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 1-2 blocks on a level and climbing one flight at normal conditions results in angina.

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

UNSTABLE ANGINA: is a changing pattern of angina that has distinctly worsened in severity and frequency in comparison to the patient's previous pattern. The chest discomfort or unstable angina, while similar in quality to stable angina, may be more intense and persist for longer periods of time, and may occur at rest.

ISCHEMIC PAIN IN ASSOCIATION WITH MYOCARDIAL INFARCTION: This box should be checked if patient experiences pain only during a documented myocardial infarction. It is an episode of chest discomfort, similar in quality to angina, but different in that the discomfort persists or waxes and wanes for more than 30 minutes, is usually more intense, is unrelieved by sublingual nitroglycerin (often requires opiates for relief).

ANGINAL EQUIVALENTS OR ATYPICAL ANGINA: *Anginal equivalents* include symptoms of myocardial ischemia other than angina such as shortness of breath either at rest or exertion, exertional fatigue, nausea, or unexplained diaphoresis. *Atypical angina* is defined as either a) chest discomfort not characteristic for angina but with precipitating factors (i.e., exercise, emotional stress, cold exposure, etc.) typical for triggering myocardial ischemia, or b) chest discomfort consistent with angina but with unusual precipitating causes or triggers. Both anginal equivalents and atypical angina are often expressions of myocardial ischemia in patients who do not have classic angina. Many of these patients have been considered to have "silent" ischemia but on more direct questioning will admit to the symptoms mentioned above.

PROLONGED ACTING INSULIN: Record NPH, Lente, Ultralente, and Glargine.

SHORT ACTING INSULIN: Record Regular, Lispro, and Insulin Aspart.

Note: Record pre-mixed insulin (e.g. 75/25, 70/30, 50/50) under “Prolonged Acting”. Enter zero for “Short Acting” when recording pre-mixed insulin.

Date Entered_____
Initials_____

BARI 2D CLOSEOUT CHECKLIST

BARI 2D ID __ __ __ __ __ __ __ __ __ __ __ __

---

1. Did the patient have a pre-closeout visit three months prior to Closeout?

No 0 ( ) →

1.1 Reason:

Patient Refused	1( )
Patient Died	2( )
Patient Lost-to Follow-up	3( )
Patient was a No-Show	4( )
Other	5( )

Specify: _____

Yes 1( ) →

1.2 Date of Visit: ____/____/_____
mm dd yyyy

2. Did you discuss closeout and the transition out of BARI 2D with the patient prior to closeout?

No 0 ( )

Yes 1 ( )

3. Was the patient mailed the letter one month prior to Closeout?

No 0 ( ) →

3.1 Reason:

Address Unknown	1( )
Given at Clinic Visit	2( )
Returned by Post Office	3( )
Other	4( )

Specify: _____

Yes 1( ) →

3.2 Date Letter Mailed: ____/____/_____
mm dd yyyy

4. Did the patient have a Closeout visit?

No 0 ( ) →

4.1 Reason:

Patient Refused	1( )
Patient Died	2( )
Patient Lost-to Follow-up	3( )
Patient was a No-Show	4( )
Other	5( )

Specify: _____

Yes 1( ) →

4.2 Date of Visit: ____/____/_____
mm dd yyyy

5. Was consent obtained to participate in the Post-Treatment Follow-up Phase?

No 0 ( ) →

5.1 Reason (check all that apply):

		No	Yes
5.1.1	Health reasons	0 ( )	1 ( )
5.1.2	Dissatisfaction with study care	0 ( )	1 ( )
5.1.3	Monetary reasons	0 ( )	1 ( )
5.1.4	Study burden	0 ( )	1 ( )
5.1.5	Death	0 ( )	1 ( )
5.1.6	Incarceration	0 ( )	1 ( )
5.1.7	Other	0 ( )	1 ( )

Specify _____
_____

Yes 1( ) →

5.2 Date of Consent: ____/____/_____
mm dd yyyy

……..……..

Name code of person completing form ___ ___ ___ ___ ___

Date of form completion ____/____/_____
mm dd yyyy

Date Entered _____
Initials_____
Date Verified_____
Initials_____

BARI 2D CEREBROVASCULAR ACCIDENT FORM

BARI 2D ID__ __ __ __ __ __ __ __ __ __ __ __

Patient Name_____

1. Record date and time of onset of stroke:

   1.1 Date____/____/____
   mm dd yyyy

   1.2 Time ____:____ (use military time)
   hh mm

2. Record duration of neurologic deficit due to stroke:

   < 24 hours 1 ( )
   1-7 days 2 ( )
   > 7 days 3 ( )

3. Was the stroke confirmed by a CT or MRI scan?

   No 0 ( )
   Yes 1 ( )

4. Record the type of stroke:

   Hemorrhagic 1 ( )
   Ischemic 2 ( )
   Indeterminant 3 ( )

5. Did the stroke occur during or within 24 hours after a revascularization procedure?

   No 0 ( )
   Yes 1 ( )→

Revascularization Procedure date and time:	Type of Revascularization Procedure (CABG/PCI):
5.1.1 ____/____/_____5.1.2 ____:____ (use military time) mm dd yyyy hh mm	5.1.3 CABG 1( ) PCI 2( )
5.2.1 ____/____/_____5.2.2 ____:____ (use military time) mm dd yyyy hh mm	5.2.3 CABG 1( ) PCI 2( )

6. Did the patient report symptoms of hypoglycemia in the 2 hours preceding the stroke?

   No 0 ( )
   Yes 1 ( )

7. Was blood glucose measured prior to or in association with the stroke?

   No 0 ( )
   Yes 1 ( ) →

   7.1 Record blood glucose value*: _____ mg/dl_____mmol/L

   7.2 Record date and time of glucose reading:

   7.2.1 Date ____/____/____
   mm dd yyyy

   7.2.2 Time ___:____ (use military time)
   hh mm

   7.3 Did patient receive treatment (e.g. for hypoglycemia) prior to this blood glucose measurement which may have altered the value recorded in 7.1?
   No 0 ( )
   Yes 1 ( )

   7.4 By whom was the blood glucose measured?
   Patient/ Family 1 ( )
   EMS personnel 2 ( )
   ER personnel 3 ( )
   Other 4 ( )
   Specify: _____

   7.5 Method used for blood glucose measurement:
   Blood glucose monitor 1 ( )
   Lab determination 2 ( )
   (plasma or serum)

8. Was thrombolytic therapy used to treat the stroke?

   No 0 ( )
   Yes 1 ( )

9. Did the stroke impact the patient's ability to perform activities of daily living for 4 weeks or more after the event?

   No 0 ( )
   Yes 1 ( )

10. Record the score based on the Modified Rankin Scale_____ (See page 1a)

11. Comments (Optional):

_____

_____

_____

* If there are two or more glucose measurements associated with the stroke, record the value closest (in time) to the stroke and prior to any treatment that would alter the blood glucose measurement.

……

Name code of person completing form___ ___ ___ ___ ___
Date of form completion ____/_____/_____
mm dd yyyy

MODIFIED RANKIN SCALE

Score	Description
0	No symptoms at all
1	No significant disability despite symptoms; able to carry out all usual duties and activities
2	Slight disability; unable to carry out all previous activities, but able to look after own affairs without assistance
3	Moderate disability; requiring some help, but able to walk without assistance
4	Moderately severe disability, unable to walk without assistance and unable to attend to own bodily needs without assistance
5	Severe disability; bedridden, incontinent and requiring constant nursing care and attention
6	Death

Score (0-6): _____

Form not entered into MATRIX – variable names not required

BARI 2D CEREBROVASCULAR ACCIDENT CHECKLIST

[Do not enter this Checklist into MATRIX]

BARI 2D ID__ __ __ __ __ __ __ __ __ __ __ __ Date of CVA _____/_____/_____
mm dd yyyy

The following information must be completed and sent to the Coordinating Center Data Manager for your site. Use this checklist to verify that all relevant information has been collected. Keep all information about a patient's cerebrovascular accident (stroke) until all documentation (see * items) has been collected, then send by U.S. mail or express mail the **ENTIRE PACKET** along with this completed checklist. **Patient and family names must be blanked out from each page of all documents and replaced with the BARI 2D ID.**

1.	Cerebrovascular Accident Data Form entered into MATRIX	Yes ( )	Pending ( )
2.*	Hospital records including a description of the clinical event	Yes ( )	No ( )
3.*	Summary report for CT scan	Yes ( )	No ( )
4.*	Summary report for MRI scan	Yes ( )	No ( )

Form not entered into MATRIX – variable names not required

BARI 2D MORTALITY CHECKLIST
[Do not enter this Checklist into MATRIX]

BARI 2D ID__ __ __ __ __ __ __ __ __ __ __ __ Date of Death _____/_____/_____
mm dd yyyy

The following information must be completed and sent to the Coordinating Center. Use this checklist to verify that all relevant information has been collected. Keep all information about a patient's death until all documentation (see * items) has been collected, then send by U.S. mail or express mail the **ENTIRE PACKET** along with this completed checklist. **Patient and family names must be blanked out from each page of all documents and replaced with the BARI 2D ID.**

1.	Serious Adverse Event Form faxed to CC	Yes ( )	Pending ( )
2.	ID Inactivation Form for "Deceased" entered into MATRIX	Yes ( )	Pending ( )
3.	Mortality Data Form entered into MATRIX	Yes ( )	Pending ( )
4.	Final Clinic Visit Monitoring Form entered into MATRIX	Yes ( )	Pending ( )
5.*	Principal Investigator's Report enclosed	Yes ( )	No ( )
6.*	Death Certificate enclosed	Yes ( )	No ( )
7.*	Coroner's Report enclosed (if appropriate)	Yes ( )	No ( )
8.	Economics Core Lab notified	Yes ( )	No ( )
9.	Did the patient die within 30 days following a cardiac procedure?	Yes ( ) →	No ( ) → SKIP TO QUESTION 10

9.1 Check the procedure(s): Procedure reports and signature are required.

9.1.1* PCI ( ) → Cath Lab report enclosed No ( ) Yes ( ) → Complete PCI Procedure Form (PP)

9.1.2* CABG ( ) → Surgical report enclosed No ( ) Yes ( ) → Complete Surgery Form (SP)

9.2 Has the surgeon and/or PCI operator signed the P.I.'s report? No ( ) Yes ( )

10. Did death occur during a hospitalization?

No ( )

Yes ( ) →

10.1 Were ECGs performed during this hospitalization?

No ( ) Yes ( ) → 10.1.1 Copies sent to CEL? No( ) Yes ( )

10.2 Were suspected MIs reported during this hospitalization?

No ( ) Yes ( ) → Complete Suspected MI Checklist (MIL)

10.3 Were cardiac enzymes drawn during hospitalization?

No ( ) Yes ( ) →

10.3.1 Were enzyme lab reports sent to CEL?

No ( ) Yes ( )

BARI 2D

PRINCIPAL INVESTIGATOR'S REPORT OF PATIENT DEATH

Patient BARI 2D ID: __ __ __ __ __ __ __ __ __ __ __

Date of Death: ____ /____ /____

Circumstances of Death (provide a typed description; may attach additional pages):

Respectfully submitted to the BARI 2D Coordinating Center by:

Principal Investigators -- **BOTH REQUIRED**:

Diabetology: Sign _____
Print _____

Cardiology: Sign _____
Print _____

Other investigators/personnel -- OPTIONAL:

(1) Role: _____ Sign _____
Print _____
(2) Role: _____ Sign _____
Print _____
(3) Role: _____ Sign _____
Print _____

DR 1/02

Date Entered _____
Initials_____

Date Verified_____
Initials_____

BARI 2D ANNUAL FOLLOW-UP FORM-2

CARDIAC / DIABETES STATUS

BARI 2D ID__ __ __ __ __ __ __ __ __ __ __ __

Patient Name_____

SECTION A: FOLLOW-UP INFORMATION

1. Date of evaluation: ____/____/____
   mm dd yyyy

2. Indicate follow-up period:

1 year	1( )
2 years	2( )
3 years	3( )
4 years	4( )
5 years	5( )
6 years	6( )

3. Did the clinic visit occur at a BARI 2D facility (i.e. primary or satellite site)?

No	0 ( )
Yes	1 ( )

4. Did BARI 2D personnel conduct the visit?

No	0 ( )
Yes	1 ( )

SECTION B: PATIENT STATUS

1. Indicate patient's current level of physical activity prior to any recent acute event or hospitalization:

Sedentary	1( )
Mild	2( )
Moderate	3( )
Strenuous	4( )

2. Gender:

Male 1( )

Female 2( ) →

2.1 Record menopausal status

Pre-menopause	1( )
Peri-menopause	2( )
Post-menopause	3( )
Surgical menopause	4( )

2.1.1 In the last 12 months has the patient taken hormone replacement therapy?

No 0( )

Yes 1( ) →

2.1.1.1 Specify therapy:

Estrogen only	1( )
Estrogen/ Progesterone	2( )
Other	3( )

Specify:_____

_____

_____

3. In the opinion of the clinician, does the patient have intermittent claudication?

No	0 ( )
Yes	1 ( )

SECTION B: PATIENT STATUS

4. History of **new** significant illness or therapy (not already recorded):

	No	Yes	Unknown
4.1 Carotid disease, documented by carotid bruit	0( )	1( )	-3( )
4.2 Carotid disease, documented by ultrasound or angiography	0( )	1( )	-3( )
4.3 Carotid surgery	0( )	1( )	-3( )
4.4 Carotid stent	0( )	1( )	-3( )
4.5 Non-coronary vascular surgery	0( )	1( )	-3( )
4.6 Abdominal aneurysm	0( )	1( )	-3( )
4.7 Chronic obstructive pulmonary disease	0( )	1( )	-3( )
4.8 Pulmonary edema	0( )	1( )	-3( )
4.9 Asthma	0( )	1( )	-3( )
4.10 Chronic renal dysfunction (creatinine > 1.5 mg/dl, 132.6 mmol/L)	0( )	1( )	-3( )
4.11 Malignancy	0( )	1( )	-3( )
4.12 Other	0( )	1( )	-3( )

Specify:_____

4.11.1 Record the primary site of malignancy:

Skin	1( )
Lung	2( )
Pancreas	3( )
Liver	4( )
Gastrointestinal	5( )
Breast	6( )
Prostate	7( )
Blood	8( )
Lymphoma	9( )
Other	10( )

Specify:_____

→ 4.11.1.1 Is malignancy a melanoma?
No 0( )
Yes 1( )

5. Is the patient being treated for chronic congestive heart failure?

No	0( )
Yes	1( ) →
Unknown	-3( )

5.1 Record Current New York Heart Association Functional Classification
I( ) II( ) III( ) IV( )

SECTION B: PATIENT STATUS

6. Did the patient have a history of macular edema prior to entry into BARI 2D?

No	0( )
Yes	1( )
Unknown	-3( )

7. Did the patient have a new diagnosis or worsening of macular edema since entry into BARI 2D?

No	0( )
Yes	1( ) →
Unknown	-3( )

7.1 Date of first new diagnosis or worsening of macular edema since entry into BARI 2D: _____/_____/_____ mm dd yyyy

7.2 Treatment for macular edema prescribed since entry into BARI 2D:

	No	Yes
7.2.1 Laser treatment	0( )	1( )
7.2.2 Injections in the eye	0( )	1( )
7.2.3 Other	0( )	1( )

Specify_____

8. In the opinion of the clinician is the patient following a special diet requested by a physician?

No	0( )
Yes	1( ) →
Unknown	-3( )

Specify:
(Check all that apply)

	No	Yes
8.1 Diabetic diet	0( )	1( )
8.2 Weight loss	0( )	1( )
8.3 Low sodium	0( )	1( )
8.4 Low saturated fat	0( )	1( )
8.5 Low carbohydrate	0( )	1( )
8.6 Other	0( )	1( )

Specify:_____

9. Record waist circumference:

9.1 First measurement _____cm

9.2 Second measurement _____cm

10. Record arm circumference _____cm

SECTION B: PATIENT STATUS

11. Record Supine Blood Pressure:

11.1 Right arm: Systolic _____mmHg Diastolic _____mmHg

11.2 Left arm: Systolic _____mmHg Diastolic _____mmHg

11.3 Record 30 second pulse _____beats

12. Ankle Blood Pressure:

12.1 Record arm chosen as reference:

Right 1( )
Left 2( )

	Check if unable to occlude vessel	Check if unable to perform test	SBP #1	SBP #2
12.2 Reference Arm	( )	( )	_____mmHg	_____mmHg
12.3 Right Ankle PT	( )	( )	_____mmHg	_____mmHg
12.4 Left Ankle PT	( )	( )	_____mmHg	_____mmHg

13. Appearance of Feet:

13.1 Are you able to assess the right foot?

No 0( )
Yes 1( ) →

	No	Yes
13.1.1 Deformed	0( )	1( )
13.1.2 Dry skin, callus	0( )	1( )
13.1.3 Infection	0( )	1( )
13.1.4 Fissure	0( )	1( )
13.1.5 Onychomycosis	0( )	1( )
13.1.6 Other	0( )	1( )

Specify:_____

13.2 Are you able to assess the left foot?

No 0( )
Yes 1( ) →

	No	Yes
13.2.1 Deformed	0( )	1( )
13.2.2 Dry skin, callus	0( )	1( )
13.2.3 Infection	0( )	1( )
13.2.4 Fissure	0( )	1( )
13.2.5 Onychomycosis	0( )	1( )
13.2.6 Other	0( )	1( )

Specify:_____

SECTION B: PATIENT STATUS

		RIGHT		LEFT	
14. Ulceration:	Absent	1 ( )	Absent	1 ( )
	Present	2 ( )	Present	2 ( )
	N/A	-2 ( )	N/A	-2 ( )
15. 10 gm filament test	Present (≥ 8)	1 ( )	Present (≥ 8)	1 ( )
(record number of applications	Reduced (1-7)	2 ( )	Reduced (1-7)	2 ( )
detected)	Absent (0)	3 ( )	Absent (0)	3 ( )
	N/A	-2 ( )	N/A	-2 ( )
16. Vibration perception at great toe:	Present	1 ( )	Present	1 ( )
	Reduced	2 ( )	Reduced	2 ( )
	Absent	3 ( )	Absent	3 ( )
	N/A	-2 ( )	N/A	-2 ( )
17. Ankle reflexes:	Present	1 ( )	Present	1 ( )
	Present/Reinforcement	2 ( )	Present/Reinforcement	2 ( )
	Absent	3 ( )	Absent	3 ( )
	N/A	-2 ( )	N/A	-2( )

18. In the opinion of the clinician does this patient have peripheral neuropathy?

No 0( )

Yes 1( )

19. Sitting Blood Pressure:

19.1 Record arm used for measurement:

Right 1( )

Left 2( )

		First	Second	Third
19.2	Systolic	_____ mmHg	_____ mmHg	_____ mmHg
19.3	Diastolic	_____ mmHg	_____ mmHg	_____ mmHg
19.4	Record 30 second pulse	_____beats	_____beats	_____beats

SECTION B: PATIENT STATUS

20. Standing Blood Pressure:

20.1 Is patient able to stand?

No 0( )

Yes 1( ) →

20.1.1 Record arm used for measurement:

Right 1( )

Left 2( )

20.1.2 Systolic _____ mmHg

20.1.3 Diastolic _____ mmHg

20.1.4 Record 30 second pulse _____beats

		Record Unequal Symbol if Needed*	Record Correct Unit of Measurement	
21.	Local urine creatinine:	_____	_____mg/dl	_____mmol/L
22.	Local urine albumin:	_____	_____mg/dl	_____mmol/L
23.	Local urine albumin/creatinine ratio:	_____	_____µg/mg	_____%

* If the exact value is not provided by the lab, specify the inequality symbol (<, >, ≤, ≥).

24. Has the patient had a fracture or multiple fractures in the past year?

No 0( )
Yes 1( ) → 24.1 Number of fractures in the past year: _____
Unknown -3( )

24.2 Location of Fracture(s) (**check all that apply**)	No	Yes
24.2.1 Foot/Ankle	0( )	1( )
24.2.2 Leg	0( )	1( )
24.2.3 Hip	0( )	1( )
24.2.4 Spine	0( )	1( )
24.2.5 Arm	0( )	1( )
24.2.6 Hand/Wrist	0( )	1( )
24.2.7 Other	0( )	1( )

Specify:_____

24.3 Cause of Fracture(s) (**check all that apply**)	No	Yes
24.3.1 Fall	0( )	1( )
24.3.2 Motor Vehicle Accident	0( )	1( )
24.3.3 Sports/exercise	0( )	1( )
24.3.4 Other	0( )	1( )

Specify:_____

……

Name code of person completing form ___ ___ ___ ___ ___

Date of form completion____/____/____
mm dd yyyy

PHYSICAL ACTIVITY LEVEL

Sedentary:	Very little to no physical activity. When active, walks less than 1 block or only 1 flight of stairs. Activities can include reading, needlework and stamp collecting.
Mild:	Mild physical activity includes walking 1-2 blocks on a level and climbing more than one flight of stairs at one time. No participation in sports. Activities include photography, fishing, and light gardening.
Moderate:	Walking more than 2 blocks on level at one time. Participation in sports which do not require excess exertion such as ping pong, golf, bowling, and light housework.
Strenuous:	Participation in active sports such as tennis, jogging, basketball, and swimming.

New York Heart Association Functional Classification

Class	Definition
I	No limitation of physical activity. Ordinal physical activity does not cause undue fatigue, or dyspnea.
II	Slight limitation of physical activity. Comfortable at rest, but ordinary physical activity results in fatigue, or dyspnea.
III	Marked limitation of physical activity. Comfortable at rest, but less than ordinary activity causes fatigue, or dyspnea.
IV	Unable to carry on any physical activity without symptoms. Symptoms are present even at rest. If any physical activity is undertaken, symptoms are increased.

The NYHA functional class for CHF depends upon the amount of physical activity the patient is able to perform without experiencing symptoms of fatigue or dyspnea. A patient able to ascend one flight of stairs without symptoms, or walk one block with a mild to moderate incline is classified as a New York Heart Association Class I, unless that same amount of activity resulted in excessive fatigue or dyspnea, in which case the classification is Class II. If walking from the kitchen to the living room causes symptoms, the patient is classified as Class III. Symptoms occurring at rest or with minimal activity are considered Class IV.

Date Entered _____
Initials_____

Date Verified_____
Initials_____

BARI 2D ANNUAL FOLLOW-UP FORM-1

QUESTIONNAIRE

BARI 2D ID__ __ __ __ __ __ __ __ __ __ __

Patient Name_____

SECTION A: FOLLOW-UP INFORMATION

1. Date of evaluation: ____/____/____ **FOR COORDINATOR USE ONLY**
mm dd yyyy

2. Indicate follow-up period:

1 year	1( )
2 years	2( )
3 years	3( )
4 years	4( )
5 years	5( )
6 years	6( )
7 years	7( )

SECTION B: WORK STATUS

1. Record your current work status. Do not include temporary adjustments in work status due to recent symptoms of heart disease and/or diabetes.

   (Check only one)

Working full time	1( )
Working part-time	2( )
On long-term sick leave	3( )
Homemaker	4( )
Retired	5( )
Disabled	6( )
Unemployed or looking for work	7( )
Temporarily laid off	8( )
Other	9( )

   Specify: _____

2. Have you stopped working full time in the last 12 months?

   No 0( )

   Yes 1( ) ⟶

   2.1 When did you stop working full time? ___ /___/___
   mm dd yyyy

   2.2 Was decision to stop working full time related to:

	No	Yes
2.2.1 Heart condition	( )	( )
2.2.2 Diabetes	( )	( )
2.2.3 Other health condition	( )	( )

   Specify:_____

3. Record number of persons living in household (including you) _____

4. What is your primary method of insurance?

Medicare	1( )
Other public (example: Medicaid, VA, Health Canada)	2( )
Private (example: Blue Cross, HMO)	3( )
None/self pay	4( )

SECTION C: MICHIGAN NEUROPATHY SCREENING INSTRUMENT

		No	Yes
1.1	Are your legs and feet numb?	0 ( )	1( )
1.2	Do you ever have any burning pain in your legs and feet?	0 ( )	1( )
1.3	Are your feet too sensitive to touch?	0 ( )	1( )
1.4	Do you get muscle cramps in your legs and feet?	0 ( )	1( )
1.5	Do you ever have any prickling feelings in your legs or feet?	0 ( )	1( )
1.6	Does it hurt when the bed covers touch your skin?	0 ( )	1( )
1.7	When you get into the tub or shower can you tell the hot water from the cold?	0 ( )	1( )
1.8	Have you ever had an open sore on your foot?	0 ( )	1( )
1.9	Has a doctor ever told you that you have diabetic neuropathy?	0 ( )	1( )
1.10	Do you feel weak all over most of the time?	0 ( )	1( )
1.11	Are your symptoms worse at night?	0 ( )	1( )
1.12	Do your legs hurt when you walk?	0 ( )	1( )
1.13	Are you able to sense your feet when you walk?	0 ( )	1( )
1.14	Is the skin on your feet so dry that it cracks open?	0 ( )	1( )
1.15	Have you ever had an amputation?	0 ( )	1( )

SECTION D: HEALTH BEHAVIOR

1. During the past 12 months have you consumed an average of at least one alcoholic beverage per week?

No 0( )
Yes 1( ) →

1.1 On average how many 12 oz bottles of beer **per week** did the patient consume?_____ bottles

1.2 On average how many 4 oz glasses of wine **per week** did the patient consume?_____ glasses

1.3 On average how many 1.5 oz shots of hard liquor or mixed drinks **per week** did the patient consume?_____ shots

SECTION E: QUALITY OF LIFE
(Responses must reflect those of the patient himself/herself)

1. In general, would you say your health is:

Excellent	1( )
Very good	2( )
Good	3( )
Fair	4( )
Poor	5( )

2. Compared to one year ago, how would you rate your health in general now?

Much better now than one year ago	1( )
Somewhat better now than one year ago	2( )
About the same as one year ago	3( )
Somewhat worse than one year ago	4( )
Much worse now than one year ago	5( )

3. On a scale of 0 to 100, with 0 being equal to death and 100 being equal to excellent health, what number best describes **your state of health now**? _____

SECTION E: QUALITY OF LIFE

4. We would like to know how confident you are in doing certain activities. For each of the following questions, please circle the number that corresponds to your confidence that you can do these things regularly at the present time.

4.1 Having diabetes and heart disease often means doing different tasks and activities to manage your condition. How confident are you that you can do all the things necessary to manage your condition on a regular basis?

Not at all Confident	1	2	3	4	5	6	7	8	9	10 Totally Confident

How confident are you that you can…

4.2 Do the different tasks and activities needed to manage your diabetes and heart disease so as to reduce your need to see a doctor?

Not at all Confident	1	2	3	4	5	6	7	8	9	10 Totally Confident

4.3. Reduce the emotional distress caused by your diabetes and heart disease so that it does not affect your everyday life?

Not at all Confident	1	2	3	4	5	6	7	8	9	10 Totally Confident (or no distress)

4.4 Do things other than just taking medication to reduce how much your diabetes and heart disease affect your everyday life?

Not at all Confident	1	2	3	4	5	6	7	8	9	10 Totally Confident

5. How have your feelings of confidence in your ability to manage your diabetes and heart disease **changed** since starting treatment in the BARI 2D study?

Very much better	**Somewhat better**	**A little better**	**No change**	**A little worse**	**Somewhat worse**	**Very much worse**
1( )	**2( )**	**3( )**	**4( )**	**5( )**	**6( )**	**7( )**

SECTION E: QUALITY OF LIFE

The following questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please check a number for the one answer that comes closest to the way you have been feeling.

How much of the time during the past 4 weeks …

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
6. Did you feel tired?	1( )	2( )	3( )	4( )	5( )
7. Were you discouraged by your health problems?	1( )	2( )	3( )	4( )	5( )
8. Did you feel full of pep?	1( )	2( )	3( )	4( )	5( )
9. Were you fearful about your future health?	1( )	2( )	3( )	4( )	5( )
10. Did you feel worn out?	1( )	2( )	3( )	4( )	5( )
11. Were you frustrated by your health problems?	1( )	2( )	3( )	4( )	5( )
12. Did you have enough energy to do the things you wanted to do?	1( )	2( )	3( )	4( )	5( )
13. Was your health a worry in your life?	1( )	2( )	3( )	4( )	5( )
14. Did you have a lot of energy?	1( )	2( )	3( )	4( )	5( )

15. How have your feelings of discouragement, fear, worry or frustration **changed** since starting treatment in the BARI 2D study?

Very much better	Somewhat better	A little better	No change	A little worse	Somewhat worse	Very much worse
1( )	2( )	3( )	4( )	5( )	6( )	7( )

SECTION E: QUALITY OF LIFE

The following questions are about your ability to do certain physical activities. For each question, please rate the extent to which you can do one or more of the activities at the present time. Some questions mention more than one activity. Answer according to the one activity you can do best. If you have never done an activity, or don't usually do it, answer "Don't do this for other reasons."

Can you…	**Yes, with no difficulty**	**Yes, but with some difficulty**	**No, I can't do this**	**Don't do this for other reasons**
16. take care of yourself, that is, eating, dressing bathing, and using the toilet?	1( )	2( )	3( )	4( )
17. walk indoors, such as around your house?	1( )	2( )	3( )	4( )
18. walk a block or two on level ground?	1( )	2( )	3( )	4( )
19. climb a flight of stairs or walk up a hill?	1( )	2( )	3( )	4( )
20. walk several blocks or 1 mile ?	1( )	2( )	3( )	4( )
21. run a short distance?	1( )	2( )	3( )	4( )
22. do light work around the house like dusting or washing dishes?	1( )	2( )	3( )	4( )
23. do moderate work around the house like vacuuming, sweeping floors, or carrying in groceries?	1( )	2( )	3( )	4( )
24. do heavy work around the house like scrubbing floors, or lifting or moving heavy furniture?	1( )	2( )	3( )	4( )
25. do yard work like raking leaves, weeding, or pushing a power mower?	1( )	2( )	3( )	4( )
26. have sexual relations?	1( )	2( )	3( )	4( )
27. participate in moderate recreational activities like golf, bowling, dancing, doubles tennis, or throwing a baseball or football?	1( )	2( )	3( )	4( )
28. participate in strenuous sports like swimming, singles tennis, football, basketball, or skiing?	1( )	2( )	3( )	4( )

29. How has your ability to do different physical activities (such as daily activities, walking around, or moderate to strenuous activities like running or other forms of exercise) **changed** since starting treatment in the BARI 2D study?

Very much better	**Somewhat better**	**A little better**	**No change**	**A little worse**	**Somewhat worse**	**Very much worse**
1( )	**2( )**	**3( )**	**4( )**	**5( )**	**6( )**	**7( )**

SECTION E: QUALITY OF LIFE

How have you felt or behaved during the <u>past week</u> …

	Rarely or none of the time (less than 1 day)	Some or little of the time (1-2 days)	Occasionally or a moderate amount of the time (3-4 days)	Most or all of the time (5-7 days)
30. I was bothered by things that usually don't bother me.	0( )	1( )	2( )	3( )
31. I did not feel like eating; my appetite was poor.	0( )	1( )	2( )	3( )
32. I felt that I could not shake off the blues even with help from my family or friends.	0( )	1( )	2( )	3( )
33. I felt that I was just as good as other people.	0( )	1( )	2( )	3( )
34. I had trouble keeping my mind on what I was doing.	0( )	1( )	2( )	3( )
35. I felt depressed.	0( )	1( )	2( )	3( )
36. I felt that everything I did was an effort.	0( )	1( )	2( )	3( )
37. I felt hopeful about the future.	0( )	1( )	2( )	3( )
38. I thought my life had been a failure.	0( )	1( )	2( )	3( )
39. I felt fearful.	0( )	1( )	2( )	3( )
40. My sleep was restless.	0( )	1( )	2( )	3( )
41. I was happy.	0( )	1( )	2( )	3( )
42. I talked less than usual.	0( )	1( )	2( )	3( )
43. I felt lonely.	0( )	1( )	2( )	3( )
44. People were unfriendly.	0( )	1( )	2( )	3( )
45. I enjoyed life.	0( )	1( )	2( )	3( )
46. I had crying spells.	0( )	1( )	2( )	3( )
47. I felt sad.	0( )	1( )	2( )	3( )
48. I felt people disliked me.	0( )	1( )	2( )	3( )
49. I could not get going.	0( )	1( )	2( )	3( )

SECTION F: PHYSICAL ACTIVITY QUESTIONNAIRE

*The following questions will ask you about the kinds of physical activities you do as part of your everyday living and the time you spent being physically active in the **last 7 days**. Please answer each question, even if you do not consider yourself to be an active person. Please think about the activities you do at work, as part of your house and yard work, to get from place to place, and in your spare time for recreation, exercise, or sport.*

Think about all the **vigorous** activities that you did in the **last 7 days. Vigorous** physical activities refer to activities that take hard physical effort and make you breathe much harder than normal. Think *only* about those physical activities that you did for at least 10 minutes at a time.

1. During the **last 7 days**, on how many days did you do **vigorous** physical activities like heavy lifting, digging, aerobics, or fast bicycling?

   _____ **days per week**

   ☐ **No vigorous physical activities (0)** ⟶ **Skip to question 3**

2. How much time did you usually spend doing **vigorous** physical activities on one of those days?

   _____ **hours per day**

   _____ **minutes per day**

   ☐ **Unknown/ Not Sure (-3)**

Think about all the **moderate** activities that you did in the **last 7 days**. **Moderate** activities refer to activities that take moderate physical effort and make you breathe somewhat harder than normal. Think *only* about those physical activities that you did for at least 10 minutes at a time.

3. During the **last 7 days**, on how many days did you do **moderate** physical activities like carrying light loads, bicycling at a regular pace, or doubles tennis? Do not include walking.

   _____ **days per week**

   ☐ **No moderate physical activities (0)** ⟶ **Skip to question 5**

4. How much time did you usually spend doing **moderate** physical activities on one of those days?

   _____ **hours per day**

   _____ **minutes per day**

   ☐ **Unknown/ Not Sure (-3)**

SECTION F: PHYSICAL ACTIVITY QUESTIONNAIRE

Think about the time you spent **walking** in the **last 7 days**. This includes at work and at home, walking to travel from place to place, and any other walking that you might do solely for recreation, sport, exercise, or leisure.

5. During the **last 7 days**, on how many days did you **walk** for at least 10 minutes at a time?

_____ **days per week**

☐ **No walking (0)** ⟶ **Skip to question 7**

6. How much time did you usually spend **walking** on one of those days?

_____ **hours per day**

_____ **minutes per day**

☐ **Unknown/ Not Sure (-3)**

The last question is about the time you spent **sitting** on weekdays during the **last 7 days**. Include time spent at work, at home, while doing course work and during leisure time. This may include time spent sitting at a desk, visiting friends, reading, sitting or lying down to watch television.

7. During the **last 7 days,** how much time did you spend **sitting** on a **week day**?

_____ **hours per day**

_____ **minutes per day**

☐ **Unknown/ Not Sure (-3)**

……

FOR COORDINATOR USE ONLY

Name code of person completing form ___ ___ ___ ___ ___

Date of form completion____/____/____
mm dd yyyy

Date CC Received _____

Date CC Approved _____

Date Entered_____

Initials_____

BARI 2D ID INACTIVATION FORM

Patient Name_____

Do Not enter this Form into MATRIX until approved by CC

---

1. BARI 2D ID __ __ __ __ __ __ __ __ __ __ __

2. Date of Inactivation/Last Contact: ____/____/____
   mm dd yyyy

3. Reason for Inactivation:

*1( ) Rescission of consent to be followed.

*2( ) Rescission of consent to be followed **BUT** agreeable to annual brief follow-up →

> 3.1 Participant agreeable to Economics Core Lab Followup:
> 0 ( ) No 1 ( ) Quarterly 2( ) Yearly -2 ( ) Not Applicable

*3( ) Unable to obtain continuation of informed consent due to loss of patient autonomy

*4( ) Lost to follow-up (See form instructions for acceptable criteria)

5( ) This category has been deleted.

6( ) Deceased → 3.2 Date of Death ___/____/_____ mm dd yyyy → Complete Mortality Form

7( ) Incarcerated

*8( ) Other → 3.3 Specify: _____

9( ) Participant transferred to another BARI 2D institution →

> 3.4 New BARI 2D ID __ __ __ __ __ __ __ __ __ __ __

4. Can the patient or next of kin be contacted for annual brief follow-up?

No 0 ( )
Yes 1 ( ) →
N/A -2 ( )

> 4.1 Participant agreeable to Economics Core Lab Followup:
> 0 ( ) No 1 ( ) Quarterly 2( ) Yearly -2 ( ) Not Applicable

5. In the clinician's opinion, the participant has been inactivated due to the following reasons: (**Check all that apply**)

		No	Yes
5.1	Health reasons	0 ( )	1 ( )
5.2	Dissatisfaction with study care	0 ( )	1 ( )
5.3	Monetary reasons	0 ( )	1 ( )
5.4	Study burden (e.g. frequency of visits, travel)	0 ( )	1 ( )
5.5	Relocation to area with no BARI 2D site	0 ( )	1 ( )
5.6	Death	0 ( )	1 ( )
5.7	Incarceration	0 ( )	1 ( )
5.8	Other	0 ( )	1 ( )

Specify _____

6. Explanation – **REQUIRED**

_____

_____

_____

_____

***Complete the PI Report of Patient Inactivation**

FAX Inactivation Form and PI report (if applicable) to:
BARI 2D CC Data Manager (412) 383-8690

……

Name code of person completing form___ ___ ___ ___ ___

Date of form completion ____/_____/____
mm dd yyyy

BARI 2D Principal Investigator
Report of Patient Inactivation
[DO NOT ENTER INTO MATRIX]

BARI 2D ID ___ ___ ___ ___ ___ ___ ___ ___ ___ ___ ___

Description of Circumstances Surrounding Patient's Inactivation

Cardiology Principal Investigator (Print Name)	**Signature**	**Date Signed**
Diabetology Principal Investigator (Print Name)	**Signature**	**Date Signed**

Fax Completed Report to: BARI 2D Coordinating Center Data Manager (412) 383-8690

Date Entered_____

Initials_____

BARI 2D ID REACTIVATION FORM

Patient Name_____

_____

1. BARI 2D ID __ __ __ __ __ __ __ __ __ __ __

2. Date of Reactivation: ____/____/____
mm dd yyyy

3. Explanation – **REQUIRED**

_____

_____

_____

_____

……

Name code of person completing form ___ ___ ___ ___ ___

Date of form completion ____/_____/____
mm dd yyyy

Date Entered _____
Initials_____

Date Verified_____
Initials_____

BARI 2D MORTALITY FORM

BARI 2D ID__ __ __ __ __ __ __ __ __ __ __ __

Patient Name_____

SECTION A: CIRCUMSTANCES SURROUNDING DEATH

1. Date of death ____/____/_____
   mm dd yyyy

2. Location at onset of terminal event

Hospital	1( )
ER	2( )
In transit to hospital	3( )
At home	4( )
At work	5( )
Recreation	6( )
Nursing home	7( )
Other	8( )

Specify:_____

3. Cardiac symptoms prior to death

Worsening	1( )
Stable	2( )
Improving	3( )
Unknown	4( )

4. Was death observed?

No	0( )
Yes	1( ) →

4.1 Medical Observation?

No	0( )
Yes	1( )

SECTION A: CIRCUMSTANCES SURROUNDING DEATH

5. Was an autopsy performed?

No 0( )

Yes 1( )

SECTION B: CHARACTERIZATION OF DEATH

	Primary (Check only one)	Secondary (Check all that apply)
1. Cause of Death		No Yes
Cardiac	1( )	0( ) 1( )
Cerebrovascular accident (stroke)	2( )	0( ) 1( )
Non Cardiac - atherosclerotic disease other than stroke	3( )	0( ) 1( )
Non Cardiac - medical (neoplasm, liver disease, etc.)	4( )	0( ) 1( )
Non Cardiac - related to elective surgery or procedure	5( )	0( ) 1( )
Diabetes Complications	6( )	0( ) 1( )
Accident/Trauma	7( )	0( ) 1( )
Suicide	8( )	0( ) 1( )
Unknown	9( )	

1.1 Cardiac Cause of Death
(Check all that apply)

	No	Yes
Sudden Cardiac Death	0( )	1( )
Definite MI	0( )	1( )
Probable MI	0( )	1( )
Congestive Heart Failure	0( )	1( )
Cardiac Procedure	0( )	1( )
Cardiogenic Shock	0( )	1( )
Other	0( )	1( )
Specify: _____		
Unwitnessed Beyond 1 hour	0( )	1( )

1.2 Record Type of Stroke
(Check only one)

Hemorrhagic 1( )

Ischemic 2( )

Indeterminant 3( )

1.3 Diabetes Complication Cause of Death
(Check all that apply)

	No	Yes
Hypoglycemia	0( )	1( )
Diabetic Ketoacidosis (DKA)	0( )	1( )
Hyperosmolar Hyperglycemic Nonketotic Coma	0( )	1( )
Diabetes-related Renal Failure	0( )	1( )
Amputation	0( )	1( )
Other	0( )	1( )
Specify: _____		
_____		

B: CHARACTERIZATION OF DEATH

2. Give time frame of death:
   Sudden (≤ 60 minutes from onset of symptoms) 1( )
   > 60 minutes from onset of symptoms 2( )
   Unknown 3( )

3. Did the patient report symptoms of hypoglycemia in the 2 hours preceding the death?
   No 0 ( )
   Yes 1 ( )

4. Was blood glucose known preceding or at time of death?
   No 0 ( )
   Yes 1 ( ) →

   4.1 Record blood glucose value*: _____ mg/dl_____mmol/L

   4.2 Record date and time of glucose reading:

   4.2.1 Date ____/____/____
   mm dd yyyy

   4.2.2 Time ___:____ (use military time)
   hh mm

   4.3 Did patient receive treatment (e.g. for hypoglycemia) prior to this blood glucose measurement which may have altered the value recorded in 4.1?
   No 0 ( )
   Yes 1 ( )

   4.4 By whom was the blood glucose measured?
   Patient/ Family 1 ( )
   EMS personnel 2 ( )
   ER personnel 3 ( )
   Other 4 ( )
   Specify: _____

   4.5 Method used for blood glucose measurement:
   Blood glucose monitor 1 ( )
   Lab determination (plasma or serum) 2 ( )

Narrative: Give brief summary of circumstances leading to death (OPTIONAL):

_____

_____

_____

_____

* If there are two or more glucose measurements associated with the death, record the value closest (in time) to the death and prior to any treatment that would alter the blood glucose measurement.

……

Name code of person completing form___ ___ ___ ___ ___
Date of form completion ____/_____/_____
mm dd yyyy

CHARACTERIZATION OF DEATH

CARDIAC: Examples include cardiogenic shock, myocardial infarction, primary cardiac arrest, chronic CHF with pulmonary embolism.

Sudden Cardiac Death: Death that occurs instantaneously or within 60 minutes after the onset of cardiac symptoms. Classification as sudden cardiac death will be made on the basis of time from onset of cardiac symptoms until death, regardless of subsequent pathologic findings. Patients who are resuscitated from cardiac arrest but die within 60 minutes after arrest will be classified as sudden death.

Definite Myocardial Infarction: When the patient had an infarction which met the criteria for a confirmed Q-wave or non-Q-wave MI as described in the Suspected MI Section.

Probable MI: Check if there was evidence highly suggestive of necrosis, but no physical documentation (no testing was performed or testing was incomplete.)

Congestive Heart Failure (CHF): Verification by a physician's statement in the medical record is required. In general, CHF is clinically manifested by one or more features including: dyspnea on exertion (shortness of breath on exertion), bilateral pedal edema, fatigue, orthopnea (sleeping on two or more pillows to facilitate breathing), paroxysmal nocturnal dyspnea (shortness of breath that awakens the patient from sleep). Other findings supporting the clinical manifestations include but are not restricted to: presence of S3 gallop by auscultation, elevated jugular venous pressure >8 cm H_20 by physical exam or radiographic evidence of pulmonary congestion.

Cardiac Procedure: Death within 30 days or within same hospitalization for a cardiac procedure such as PCI, CABG, diagnostic angiogram, etc.

Cardiogenic Shock: Defined as a systolic blood pressure less than 80 mmHg, which either persists for more than one hour or requires specific treatment for at least one hour. In general, shock is associated with a low urine output, decreased mental acuity or coma, and compensatory vasoconstriction (decrease in blood vessel caliber). Hypotension without these associated manifestations of low cardiac output will NOT be considered shock.

Other (Specify): If cardiac cause of death is other than one of the above categories, specify cause of death.

Unwitnessed Beyond 1 Hour: Death occurs more than 60 minutes after last observation of patient.

CEREBROVASCULAR ACCIDENT (STROKE): Defined as the rapid onset of a persistent neurologic deficit attributed to an obstruction or rupture of the brain arterial system. The deficit is not known to be secondary to brain trauma, tumor, infection or other cause. The deficit must last more than 24 hours unless death supervenes or there is demonstrable lesion on CT or MRI compatible with an acute stroke.

Hemorrhagic: The stroke is cause by a blood vessel rupture.

Ischemic: The stroke is caused by a clot forming in an artery. Both thrombotic strokes, where a blood clot forms inside a brain artery and blocks the artery's own flow, and embolic strokes, where a blood clot forms outside of the brain and travels into a brain artery, are considered ischemic strokes.

Indeterminant: One cannot determine whether the stroke was hemorrhagic or ischemic.

NON CARDIAC - ATHEROSCLEROTIC DISEASE OTHER THAN STROKE: Death related to atherosclerotic vascular disease but clearly not to cardiac disease.

NON CARDIAC - MEDICAL: Death clearly not related to cardiac disease or atherosclerotic vascular disease, although heart disease may be present. For example, neoplasm, liver disease, etc.

NON CARDIAC - RELATED TO ELECTIVE SURGERY OR PROCEDURE: Death as a direct result of a complication occurring during or after an elective procedure. For example, surgery for hernia, GI bleeding, etc.

DIABETES COMPLICATIONS:

Hypoglycemia: a) Sudden death within 30 minutes of a known blood glucose <40 mg/dl.

b) Death resulting from MVA, drowning, fall, injury, accident within 30 minutes of a known blood glucose <50 mg/dl.

Diabetic Ketoacidosis (DKA): Death from metabolic cause within 24 hours of documented DKA defined by absolute insulin deficiency with hyperglycemia (glucose level >300 mg/dl) with increased lipolysis, increased ketone production (ketone levels positive at 1:4 dilution of serum or greater OR beta hydroxybutyrate >2 mmol/L), and acidosis (pH < 7.30 or HCO3 < 15 mEq/L).

Hyperosmolar Hyperglycemic Nonketotic Coma (HHNC): Death within 48 to 72 hours of documented blood glucose >600 mg/dl and no other cause (e.g., MI, pancreatitis, sepsis, etc.)

Diabetes-related Renal Failure: Death with BUN >100, serum creatinine >5.0, serum potassium >6.0, urine protein >300 mg/dl or on dialysis with nephropathy or biopsy proven glomerulosclerosis, or no evidence of renal disease other than diabetic nephropathy.

Amputation: Non-traumatic amputation required for gangrene, foot ulcer, intractable infection leading to death.

Other (Specify): If diabetes cause of death is other than one of the above categories, specify cause of death.

ACCIDENT/TRAUMA: Violent death due to accident, such as automobile accident, drowning, gunshot wound, etc.

SUICIDE: Patient deliberately brings about own death.

UNKNOWN: If primary cause cannot be determined, record "unknown."

BARI 2D SUSPECTED MI FORM

Date Entered _____
Initials_____

Date Verified_____
Initials_____

BARI 2D ID__ __ __ __ __ __ __ __ __ __ __

Patient Name_____

This form to be used whenever there is reason to suspect an ischemic event. Please complete all items on this form and enter the information into MATRIX. Mail this form with the event ECGs, enzyme laboratory report and hospital information to the Core ECG Lab. Retain a copy of this form, ECGs and hospital information in the patient's study file.

1. Suspected MI date and time: 1.1 Date____/____/____ (mm dd yyyy) 1.2 Time ____:_____ (use military time) (hh mm)

2. Hospital admission date and time or ER visit date and time, whichever is first 2.1 Date____/____/____ (mm dd yyyy) 2.2 Time____:_____ (use military time) (hh mm)

3. Hospital discharge date and time, or ER visit discharge date and time, if patient not admitted 3.1 Date____/____/____ (mm dd yyyy) 3.2 Time____:_____ (use military time) (hh mm)

4. Did patient experience angina or other angina equivalent ischemic symptoms?

No 0( )
Yes 1( ) → 4.1 Duration of Symptoms _____ Minutes (-3 for unknown)

4.2 Description of Suspected MI event:

_____

_____

5. Risk Categorization:

	No	Yes	Unknown
5.1 Clinical or laboratory evidence of LV dysfunction	0( )	1( )	-3( )
5.2 Prior history of MI or ECG evidence of MI	0( )	1( )	-3( )
5.3 Increasing angina frequency or severity or duration with activity	0( )	1( )	-3( )
5.4 Angina provoked at a lower threshold	0( )	1( )	-3( )
5.5 New onset of angina within 2 weeks to 2 months of presentation	0( )	1( )	-3( )

5.6 Canadian Cardiovascular Society (CCS) Class prior to acute event:

0( ) 1( ) 2( ) 3( ) 4( ) Unknown -3( )

6. If patient was hospitalized was a cardiac revascularization procedure performed during this admission?
   No 0 ( )
   Yes 1 ( )

Revascularization Procedure date and time		Type of Revascularization Procedure (CABG/PCI)
6.1.1 ____/____/_____ mm dd yyyy	6.1.2 ____:_____ (use military time) hh mm	6.1.3 CABG 1( ) PCI 2( )
6.2.1 ____/____/_____ mm dd yyyy	6.2.2 ____:_____ (use military time) hh mm	6.2.3 CABG 1( ) PCI 2( )
6.3.1 ____/____/_____ mm dd yyyy	6.3.2 ____:_____ (use military time) hh mm	6.3.3 CABG 1( ) PCI 2( )

7. Did the patient report symptoms of hypoglycemia in the 2 hours preceding the suspected MI?
   No 0 ( )
   Yes 1 ( )

8. Was blood glucose measured prior to or in association with the suspected MI?
   No 0 ( )
   Yes 1 ( ) →

8.1 Record blood glucose value*: _____ mg/dl_____mmol/L

8.2 Record date and time of glucose reading:

8.2.1 Date ____/____/____
mm dd yyyy

8.2.2 Time ___:____ (use military time)
hh mm

8.3 Did patient receive treatment (e.g. for hypoglycemia) prior to this blood glucose measurement which may have altered the value recorded in 8.1?
No 0 ( )
Yes 1 ( )

8.4 By whom was the blood glucose measured?
Patient/ Family 1 ( )
EMS personnel 2 ( )
ER personnel 3 ( )
Other 4 ( )
Specify: _____

8.5 Method used for blood glucose measurement:
Blood glucose monitor 1 ( )
Lab determination 2 ( )
(plasma or serum)

* If there are two or more glucose measurements associated with the suspected MI, record the value closest (in time) to the suspected MI and prior to any treatment that would alter the blood glucose measurement.

……

Name code of person completing form___ ___ ___ ___ ___
Date of form completion ____/_____/_____
mm dd yyyy

BARI 2D SUSPECTED MI / ISCHEMIA CHECK LIST

Date Entered _____
Initials_____

BARI 2D ID__ __ __ __ __ __ __ __ __ __ __

Patient Name_____

_____

1. Suspected MI date and time:

____/____/____
mm dd yyyy

1.2 ____:_____(use military time)
hh mm

2. Post-Revascularization procedure MI (within 24 hours):

No 0 ( )
Yes 1 ( ) ⟶

2.1 Procedure Date ____/____/____
mm dd yyyy

2.2 Procedure Time ____:_____(use military time)
hh mm

In order to document the ischemic event please indicate whether the following information is available to send to the CEL. Please enter this form into the MATRIX system, then send this form with all available information to the CEL for event classification.

	Enclosed
3. ER Admission Sheet	No 0( ) Yes 1( )
4. Enzyme Laboratory Report	No 0( ) Yes 1( )
5. Admission Note	No 0( ) Yes 1( )
6. Discharge Summary	No 0( ) Yes 1( )
7. Completed MI Form	No 0( ) Yes1 ( ) ⟶ Complete the Suspected MI form (MI)
8. Event ECGs available	No 0( ) Yes 1( )

Complete the Resting ECG Log (RL)

……

Name code of person completing form___ ___ ___ ___ __

Date of form completion ____/_____/_____
mm dd yyyy

Date Entered _____
Initials_____

BARI 2D
NUCLEAR CARDIOLOGY ACQUISITION FORM

BARI 2D ID__ __ __ __ __ __ __ __ __ __ __

Patient Name_____

1. Category of imaging:

One Year	1 ( )	Four Year	4 ( )	Unscheduled	7 ( )
Two Year	2 ( )	Five Year	5 ( )		
Three Year	3 ( )	Six Year	6 ( )		

2. Results Available:

No 0 ( ) ⟶
Yes 1 ( )

Reason results are not available:

2.1 Patient Died 1 ( )
Patient Refused 2 ( )
Test Contraindicated 3 ( )
Reason for Contraindication:_____
Other 4 ( )
Specify Other: _____

3. Date of imaging: _____/_____/____
mm dd yyyy

4. Time of imaging: _____:_____ (use military time)
hr mm

5. Location where imaging was performed:

BARI 2D clinical site 1 ( )
Off site 2 ( ) ⟶

5.1 Specify Hospital: _____

6. Patient's anginal status at time of imaging:

Stable 1 ( ) ⟶
Unstable 2 ( )
Ischemic pain only in association with acute MI 3 ( )
No ischemic chest pain 4 ( )

6.1 Record Canadian Cardiovascular Society Classification:

I ( ) II( ) III( ) IV( )

…..……..

Name code of person completing form___ ___ ___ ___ ___

Date of form completion ____/____/____
mm dd yyyy

Date Entered_____
Initials_____

BARI 2D NOTIFICATION OF GENETICS CONSENT AND SAMPLE

BARI 2D ID __ __ __ __ __ __ __ __ __ __ __ __

---

1. Date of Genetics Consent: ____/____/____
   mm dd yyyy

2. Was a 10 ml EDTA tube sent to the Biochemistry Core Lab?

   No 0( )

   Yes 1( )

3. Genetics Sample Draw Date: ____/____/____
   mm dd yyyy

……..……..

Name code of person completing form ___ ___ ___ ___ ___

Date of form completion ____/____/_____
mm dd yyyy

BARI 2D NON-PHARMACOLOGIC INTERVENTION FORM

Date Entered _____

Initials_____

Date Verified_____

BARI 2D ID__ __ __ __ __ __ __ __ __ __ __

Patient Name_____

TO BE COMPLETED AT BASELINE AND FOLLOW-UP VISITS
Do not complete shaded questions for Baseline Visit

SECTION A: FOLLOW-UP INFORMATION

1. Date of evaluation: ____/____/____
   mm dd yyyy

2. Follow-up Period:

Year 0 ( ) → Month: Baseline 0 ( ) → Skip to page 3 question 2
1 ( ) → Quarter: 1 ( ) 2 ( ) 3 ( ) 4 ( )
2 ( )
3 ( )
4 ( )
5 ( )
6 ( )
7 ( )

Month: 1 ( ) 2 ( ) 3 ( ) 4 ( ) 5 ( ) 6 ( ) 9 ( )

Unscheduled U ( ) → Reason for unscheduled visit_____

SECTION B: PATIENT STATUS

1. Does the patient currently smoke?

No 0( ) →

1.1 Did the patient smoke since last NP visit?

No 0( )

Yes 1( ) →

1.1.1 When was smoking discontinued? ____/____/____
mm dd yyyy

1.1.2 Average daily consumption before patient stopped smoking:
_____ cigarettes per day

If patient has quit smoking since baseline, provide counseling and support to prevent smoking relapse.

Yes 1( ) →

Reinforce importance of smoking cessation for overall health.

1.2 Average daily consumption: _____ cigarettes per day

1.3 Is patient willing to quit?

No 0( )

Yes 1( ) →

Record treatment prescribed during this clinic visit:

	No	Yes
1.3.1 Practical counseling	0( )	1( )
1.3.2 Bupropion	0( )	1( )
1.3.3 Nicotine replacement therapy	0( )	1( )
1.3.4 Smoking cessation program	0( )	1( )
1.3.5 Other	0( )	1( )

Specify: _____

1.4 Have smoking cessation treatments been implemented previously?

No 0( )

Yes 1( ) →

Record treatment attempted:

	No	Yes
1.4.1 Practical counseling	0( )	1( )
1.4.2 Bupropion	0( )	1( )
1.4.3 Nicotine replacement therapy	0( )	1( )
1.4.4 Smoking cessation program	0( )	1( )
1.4.5 Other	0( )	1( )

Specify: _____

SECTION B: PATIENT STATUS

2. Does the patient have a current* exercise prescription from a cardiologist or his/her designee?

No 0( )
Yes 1( ) ⟶

2.1 In the clinician's opinion, is the patient following the prescription?

Always/ Usually 1( )
Sometimes 2( )
Rarely/ Not at all 3( )

3. Has the cardiologist cleared this patient for unsupervised moderate intensity exercise?

No, permanent restriction 1( )
Not at this time, may be cleared in future 2( )
Yes 3( )

4. Has the patient received exercise counseling as part of this visit?

No 0( )
Yes 1( )

* "**Current**" is defined as within the past year. If any major clinical events (e.g. MI, stroke) have occurred in the past year, the "current" exercise prescription must be reviewed to take these events into account.

SECTION B: PATIENT STATUS

5. Does the patient exercise regularly*?

Educate/reinforce importance of exercise for overall health as appropriate. An exercise prescription is required at baseline as outlined in the BARI 2D Exercise protocol. In addition, the exercise prescription should be reviewed and updated every year and following any serious clinical event.

No 0( ) ⟶

5.1 Record why not:

Contraindicated Condition	1( )
Patient refused	2( )
Other	3( )

Specify: _____

Yes 1( ) ⟶

Reinforce Borg Scale Use

Record the type of exercise the patient does:

	No	Yes	
5.2 Resistance training	0( )	1( ) ⟶	5.2.1 How many times per week? _____times per week 5.2.2 Average duration of each session? _____minutes
5.3 Flexibility training	0( )	1( ) ⟶	5.3.1 How many times per week? _____times per week 5.3.2 Average duration of each session? _____minutes
5.4 Endurance training	0( )	1( ) ⟶	5.4.1 How many times per week? _____times per week 5.4.2 Average duration of each session? _____minutes
5.5 Other	0( )	1( )	

Specify: _____

* "**Regular**" exercise means the patient exercises at least one day a week. The exercise may be an organized group program, a doctor-prescribed individual program, or a patient-initiated activity.

SECTION B: PATIENT STATUS

6. Does the patient use a pedometer?

No 0( ) →

6.1 Record why not:
- Contraindicated condition 1( )
- Patient refused 2( )
- Other 3( )
  - Specify:_____

Yes 1( ) →

Record the number of steps for 3 consecutive days as logged by the patient:

6.2 Day 1 _____ # of steps

6.3 Day 2 _____ # of steps

6.4 Day 3 _____ # of steps

7. Has the patient received dietary counseling as part of this clinic visit?

Dietary counseling is required at baseline, 3 month and annual follow-up with additional counseling as outlined in the BARI 2D Nutrition protocol.

No 0( )

Yes 1( ) →

7.1 Was counseling by a registered dietitian?
- No 0( )
- Yes 1( )

8. In the clinician's opinion, is the patient following his/her nutrition prescription?

Always/ Usually 1( )

Sometimes 2( ) →

Rarely/ Not at all 3( ) →

Reinforce nutrition education

9. Is BMI >25 Kg/m^2?

No 0( )

Yes 1( ) →

Patient should be advised to lose 10% of his/her body weight over a 6 month period.

Record interventions implemented at this clinic visit:

	No	Yes
9.1 Xenical	0( )	1( )
9.2 Nutrition counseling	0( )	1( )
9.3 Exercise counseling	0( )	1( )
9.4 Other	0( )	1( )

Specify: _____

10. Since the last NP visit, has the patient undergone bariatric (weight loss) surgery?

No 0( )
Yes 1( ) ⟶
Unknown -3( )

10.1 Date of Surgery: ____/____/____
mm dd yyyy

10.2 Type of bariatric surgery performed: (**Check only one**)

Gastric bypass (including Roux-en-Y)	1( )
Biliopancreatic diversion (BPS)	2( )
Biliopancreatic diversion with duodenal switch (BPDS)	3( )
Adjustable band	4( )
Sleeve gastrectomy	5( )
Other	6( )

Specify:_____

10.3 Method of surgical procedure: (**Check only one**)

Laparoscopic	1( )
Laparoscopic converted to open	2( )
Open	3( )

11. Does the patient monitor blood glucose at home?

No 0( )
Yes 1( ) ⟶

11.1 Record frequency of monitoring:

Less than once a week	1( )
Once per week	2( )
More than once per week, but not daily	3( )
Once per day	4( )
Twice per day	5( )
More than twice per day	6( )

12. In the clinician's opinion, is the patient adequately following foot care guidelines?

No 0( ) ⟶ **Reinforce foot care education**
Yes 1( )

13. Has the patient had a dilated eye exam since the last NP visit?

No 0( )
Yes 1( )

……..

Name code of person completing form___ ___ ___ ___ ___
Date of form completion____/____/____
mm dd yyyy

Borg Scale

Rate of Perceived Exertion (RP)		
1	Very Light	Sedentary, Rest to Moderate ADL every day
2	Light	Heavy ADL to Gentle walking, at least 3 days/week
3	Moderate	Walking >5 days to Gentle exercise routine, 3-5 days/week
4	Hard	35-39 minutes Serious exercise routine, 3-5 days/week
5	Very Hard	60-90 minutes Serious exercise routine, 5-7 days/week
6	Maximum	>Level 5 - the individual's maximum every day

Date Entered _____
Initials_____

BARI 2D NOTIFICATION OF PATIENT CONSENT
REQUIRED FOR

U. S. IND # 62577
CANADA HPB CONTROL # 073613

Combined Insulin and Rosiglitazone Therapy

BARI 2D ID__ __ __ __ __ __ __ __ __ __ __

Combinations covered by consent obtained:	1.Date consent obtained	2. Has combination therapy started?		3. Date started?
Avandia & Insulin	____/____/____ mm dd yyyy	No ( )	Yes ( )	____/____/____ mm dd yyyy
Avandamet & Insulin	____/____/____ mm dd yyyy	No ( )	Yes ( )	____/____/____ mm dd yyyy

……..…..

Name code of person completing form ___ ___ ___ ___ ___

Date of form completion____/____/_____
mm dd yyyy

Date Entered _____

Initials_____

BARI 2D OUTSIDE OF PROTOCOL STANDARDS FORM

Patient Name_____

OP ID#_____

1. BARI 2D ID __ __ __ __ __ __ __ __ __ __ __

2. Category of variation (**Check only one**):

1( ) Ineligible patient entered into study

2( ) Initial procedure of revascularization arm not performed within 4 weeks

2.1 Indicate Reason for delay:

Difficulty in Scheduling Procedure at Institution	1( )
Delay for Clinical Reasons	2( )
Delay by Patient for Personal Reasons	3( )
Patient Refused Treatment Assignment	4( )
Other	5( )
Specify:_____	

3( ) Surgeon other than certified BARI 2D surgeon at initial BARI 2D procedure

4( ) PCI Operator other than certified BARI 2D PCI Operator at initial BARI 2D procedure

5( ) Scheduled Follow-up missed or form(s) not completed (CM, NP, FD1-2, AFD)

2.2 Follow-up period:

Year 0 ( ) → Month: Baseline 0 ( )

1 ( ) 1 ( )

2 ( ) 2 ( )

3 ( ) 3 ( )

4 ( ) 4 ( )

5 ( ) 5 ( )

6 ( ) 6 ( )

9 ( )

Quarter 1 ( )

2 ( )

3 ( )

4 ( )

2.3 Were all scheduled forms for this time point missed?

No 0 ( ) → 2.3.1 Check each missed form:

Yes 1 ( )

	No	Yes
CM	0( )	1( )
NP	0( )	1( )
FD1	0( )	1( )
FD2	0( )	1( )
AFD	0( )	1( )

2.4 Did the patient experience any events (stroke, suspected MI, severe hypoglycemia, revascularization procedure) since the last clinic visit or missed scheduled visit whichever occurred last?

No 0 ( )
Yes 1 ( ) →

2.4.1 Check all that apply:

	No	Yes	
Stroke	0 ( )	1 ( ) →	Complete CVA form
Suspected MI	0 ( )	1 ( ) →	Complete MI form
Severe Hypoglycemia	0 ( )	1 ( ) →	Complete SH form
PCI	0 ( )	1 ( ) →	Complete PP form
CABG	0 ( )	1 ( ) →	Complete SP form

6( ) This category has been deleted.

7( ) Other
Specify: _____

3. Explanation of variation – **REQUIRED**

_____

_____

_____

_____

_____

_____

……

Name code of person completing form ___ ___ ___ ___ ___
Date of form completion ____/_____/____
mm dd yyyy

BARI 2D PCI PROCEDURE FORM

Date Entered_____
Initials_____

Date Verified_____
Initials_____

BARI 2D ID __ __ __ __ __ __ __ __ __ __ __ __

Patient Name_____

---

1. Date of PCI: ____/____/____
   mm dd yyyy

2. Approximate procedure start time ____:_____(use military time)
   hh mm

3. Category of PCI:

   Assigned BARI 2D Revascularization 1( )

   Other 2( ) →

Primary reason for revascularization: (**Check all that apply**)	No	Yes
3.1 Acute coronary syndrome/acute event	0( )	1( )
3.2 Severe symptoms	0( )	1( )
3.3 Worsened ischemia	0( )	1( )
3.4 Unsatisfactory results of recent intervention	0( )	1( )
3.5 Objective evidence of CAD progression	0( )	1( )
3.6 Other	0( )	1( )
Specify: _____		

4. Is this a subsequent stage of a previous PCI procedure?

   No 0( )

   Yes 1( ) →

   4.1 Date of first stage of revascularization procedure:
   ____/____/____
   mm dd yyyy

   4.2 Time of first stage of revascularization procedure:
   ___:_____ (use military time)
   hh mm

5. BARI 2D PCI Operator I.D.___ ___ ___ ___
   (enter 0000 if Non-BARI 2D PCI operator)

6. Revascularization priority:

   Elective 1( )

   Urgent 2( )

   Emergency 3( )

7. Was this procedure a repeat PCI for abrupt reclosure?

No 0( )
Yes 1( ) → 7.1 List redilated segment number code(s) ____,____,____

8. Patient's anginal status at time of PCI:

Stable 1( ) → 8.1 Record Canadian Cardiovascular Society Classification: I( ) II( ) III( ) IV( )
Unstable 2( )
Acute MI 3( )

9. Therapy Pre-Procedure (within 48 hours):	No	Yes
9.1 Beta Blocker	0( )	1( )
9.2 Calcium Channel Blocker (verapamil, diltiazem)	0( )	1( )
9.3 Calcium Channel Blocker (all others)	0( )	1( )
9.4 Nonsublingual Nitrate	0( )	1( )
9.5 Sublingual Nitrates or Nitro spray	0( )	1( )
9.6 IV Nitroglycerin	0( )	1( )
9.7 Antiarrhythmic agent	0( )	1( )
9.8 Diuretic	0( )	1( )
9.9 ACE Inhibitor	0( )	1( )
9.10 Angiotensin Receptor Blocker	0( )	1( )
9.11 Vasodilator (other than the above)	0( )	1( )
9.12 Digitalis or derivative	0( )	1( )
9.13 Inotropic agent	0( )	1( )
9.14 Alpha Blocker	0( )	1( )
9.15 Aspirin	0( )	1( )
9.16 Ticlopidine/Clopidogrel	0( )	1( )
9.17 Antiplatelet agent other than ticlopidine, clopidogrel (includes persantine/sulfinpyrazone)	0( )	1( )
9.18 Heparin (includes low molecular weight heparin)	0( )	1( )
9.19 Warfarin	0( )	1( )
9.20 Thrombolytic therapy	0( )	1( )
9.21 IIb/IIIa Receptor Antagonist	0( )	1( )
9.22 Lipid lowering agent	0( )	1( )
9.23 Intra Aortic Balloon Pump	0( )	1( )
9.24 Aldosterone Receptor Antagonist	0( )	1( )

10. Approach:

Brachial 1( ) Femoral 2( ) Radial 3( ) Other 4( )
Specify:_____

BARI 2D PCI Device Codes

	Code	Device
Atherectomy	A1	Directional Coronary Atherectomy (DCA)
	A2	Transluminal Extraction Catheter (TEC)
	A3	Rotational Atherectomy (Rotablator)
	A4	Cutting balloon
Balloon	B1	Balloon
Coil	C1	Platinum micro-coil (occlusion device)
Distal Protection Device	E1	Percusurge
	E2	Filter device
Laser	L1	Laser
Radiation	R1	Beta radiation
	R2	Gamma radiation
Stent	S1	Non-drug eluting
	S2	Drug eluting - not specified
	S3	Drug eluting - Cypher
	S4	Drug eluting – Taxus
	S5	Jomed stent
Thrombectomy	T1	Angio jet catheter
	T2	Hydrolizer
	T3	Acolysis
	T4	SCIMED Rescue Heart Techno
Other device	O1	Device not listed*
None	0	Device not used

* If "Other device", notify Coordinating Center and a device code will be assigned.

BARI 2D Medication Codes

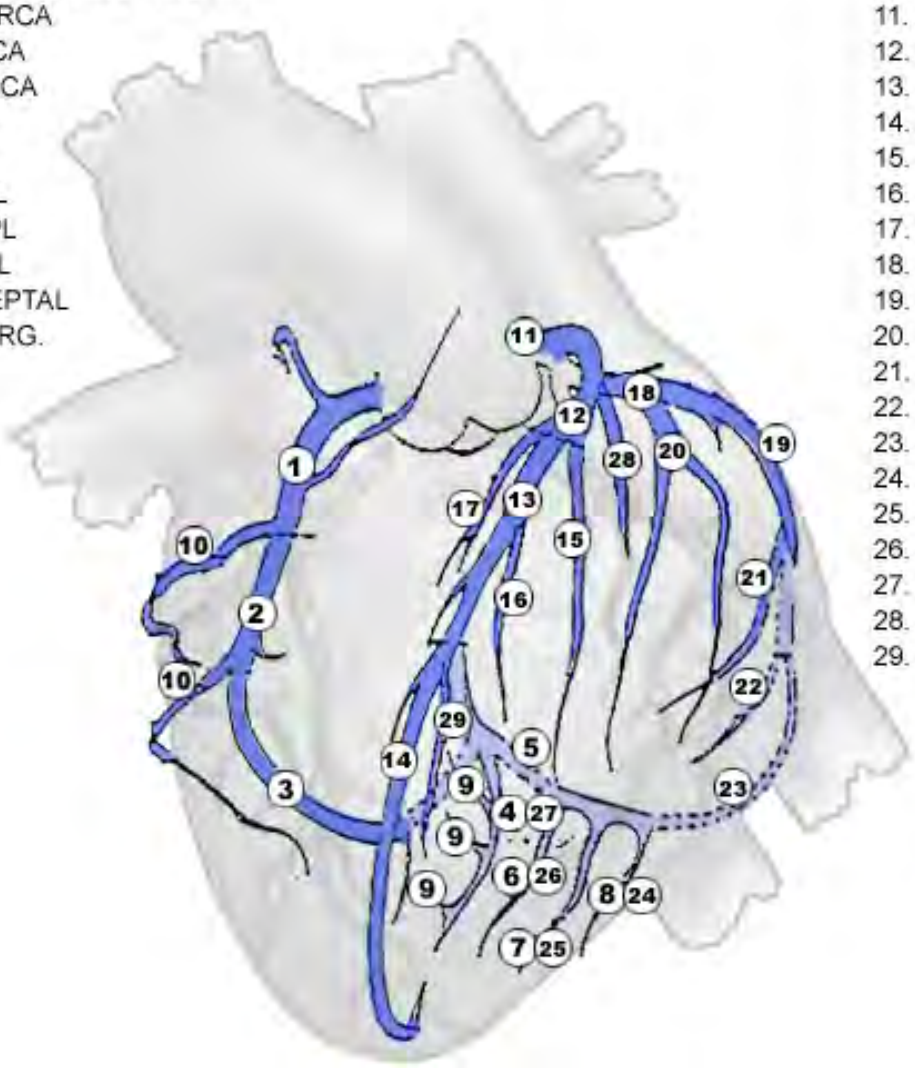
(record only medications delivered via intracoronary route, exclude routine or prophylactic use)

M1	Vasodilator
M2	Thrombolytic
M3	Calcium channel blocker
M4	Platelet antagonist
M5	Antiarrhythmic
0	None

BARI 2D CORONARY TREE DIAGRAM

RIGHT CORONARY ARTERY

1. PROX RCA
2. MID RCA
3. DIST RCA
4. RPDA
5. RPAV
6. 1st RPL
7. 2nd RPL
8. 3rd RPL
9. INF. SEPTAL
10. AC MARG.



LEFT CORONARY ARTERY

11. LMCA
12. PROX LAD
13. MID LAD
14. DIST LAD
15. 1st DIAG
16. 2nd DIAG
17. 1st SEPTAL
18. PROX CX
19. MID CX
20. 1st OB MARG
21. 2nd OB MARG
22. 3rd OB MARG
23. LAV
24. 1st LPL
25. 2nd LPL
26. 3rd LPL
27. LPDA
28. RAMUS
29. 3rd DIAG

11. Dilatation Data: Number of intended lesions_____
(to be done during this visit to cath lab)

	Intended Lesions A	B	C	D	E
11.1 Segment number code (refer to diagram on page 2b)	____	____	____	____	____
11.2 Stenosis % before dilatation (initial visual assessment)	____	____	____	____	____
11.3 Check if lesion was not attempted and skip to question 12 for this lesion	( )	( )	( )	( )	( )
11.4 Check if IVUS was used for lesion	( )	( )	( )	( )	( )
11.5 Devices used (in order) (refer to code list on page 2a)	____	____	____	____	____
	____	____	____	____	____
	____	____	____	____	____
	____	____	____	____	____
	____	____	____	____	____
	____	____	____	____	____
	____	____	____	____	____
	____	____	____	____	____
	____	____	____	____	____
	____	____	____	____	____
11.6 Medications delivered via intracoronary route (in order) (refer to code list on page 2a)	____	____	____	____	____
	____	____	____	____	____
	____	____	____	____	____
	____	____	____	____	____
11.7 Stenosis % after intervention (initial visual assessment)	____	____	____	____	____
11.8 TIMI Flow after intervention	____	____	____	____	____
11.9 Lesion Complications (record if occurred during PCI)					
11.9.1 Abrupt reclosure	____	____	____	____	____
11.9.2 Perforation	____	____	____	____	____
11.9.3 Embolization	____	____	____	____	____
11.9.4 Side branch occlusion	____	____	____	____	____
11.9.5 Persistent flow reduction	____	____	____	____	____
11.9.6 Major dissection	____	____	____	____	____
11.9.7 Other lesion complication	____	____	____	____	____

Specify:_____

12. For any intended lesion, was the change in stenosis between pre- and post-procedure less than 20%, or stenosis post-procedure 50% or greater (by initial visual assessment)?

No 0 ( )

Yes 1 ( )

		Intended Lesions				
		A	B	C	D	E
12.1	Segment number code	___	___	___	___	___

12.2 Check primary reason for above: (**Check only one**)

Inability to cross the lesion:						
Inability to enter the artery	1( )	( )	( )	( )	( )
Inability to pass wire	2( )	( )	( )	( )	( )
Inability to pass device	3( )	( )	( )	( )	( )
Other cause	4( )	( )	( )	( )	( )
Specify:_____						
Inability to dilate the lesion with balloon:						
Patient complication	5( )	( )	( )	( )	( )
Rigidity of the lesion	6( )	( )	( )	( )	( )
Technical failure	7( )	( )	( )	( )	( )
Other cause	8( )	( )	( )	( )	( )
Specify:_____						
Inability to stent the lesion:						
Unable to position stent	9( )	( )	( )	( )	( )
Failure to deploy stent	10( )	( )	( )	( )	( )
Failure to completely dilate stent	11( )	( )	( )	( )	( )
Other cause	12( )	( )	( )	( )	( )
Specify:_____						
Intended lesion was not attempted:						
Clinical reason	13( )	( )	( )	( )	( )
Technical reason	14( )	( )	( )	( )	( )

BARI 2D IIb/IIIa Receptor Antagonist Codes

	Code	Agent
Intravenous	I1	Abciximab (ReoPro)
	I2	Eftifibatide (Integrilin)
	I3	Tirofiban (Aggrastat)
	I4	Lamifaban
Oral	O1	Orbofiban
	O2	Sibrafiban
	O3	Xemlofiban
	O4	Kierval - PM

13. Cardiac–related medication used **<24 hours prior to or during** procedure: (**Check all that apply**)

13.1 Aspirin	No	0( )	Yes	1( )
13.2 Clopidogrel	No	0( )	Yes	1( )
13.3 Ticlopidine	No	0( )	Yes	1( )
13.4 IIb/IIIa receptor antagonist	No	0( )	Yes	1( ) →
13.5 Heparin	No	0( )	Yes	1( )
13.6 Low molecular weight (fractionated) heparin	No	0( )	Yes	1( )
13.7 Other	No	0( )	Yes	1( )

Specify:_____

13.4.1 Circumstances:
Planned 1( )
Bailout 2( )

13.4.2 Agent type code ____
(see back of previous page)

14. Medication used **after** the procedure:

14.1 Heparin No 0( ) Yes 1( ) →

(Check all that apply)
14.1.1 Type(s) of heparin: unfractionated ( ) fractionated ( )
14.1.2 Mode(s) of administration: intravenous ( ) subcutaneous ( )

15. Were other/adjunctive procedures performed for coronary disease?

No 0( ) Yes 1( ) →

15.1 Adjunctive operative revascularization No 0( ) Yes 1( ) →

15.1.1 Date of Procedure:
___/____/____
mm dd yyyy

15.2 Laser Myocardial Revascularization No 0( ) Yes 1( ) ↓

15.2.1 Date of procedure: ____/____/____
mm dd yyyy

15.2.2 Type of procedure: TMR 1( ) PMR 2 ( )

15.2.3 Device type:_____

15.2.4 Number of channels created:_____

15.2.5 Territory: (**Check all that apply**)
Right ( ) Left ( ) Circumflex ( )

15.2.6 Was procedure successful? No 0( ) Yes 1( )

15.3 Other: No 0( ) Yes 1( ) ↓

15.3.1 Procedure type:_____

15.3.2 Date of Procedure: ___/____/____
mm dd yyyy

LIST OF EVENTS

EVENTS

1. Non-fatal cardiac arrest requiring CPR or countershock
2. Suspected MI* → Fill out Suspected MI Checklist (MIL)

3. Congestive Heart Failure (isolated)
4. Pulmonary Edema (cardiac)
5. Cardiogenic shock
6. Cardiac tamponade
7. Hemorrhage requiring transfusion
8. Hypersensitivity reaction
9. Hypotension requiring treatment

NEUROLOGIC

10. Transient cerebrovascular event, 24 hours or less
11. Cerebrovascular accident (stroke) → Fill out CVA Form
12. Dementia
13. Coma

VASCULAR

14. Arterial embolus of extremity or loss of pulse requiring treatment

PULMONARY

15. Respiratory failure including non-cardiac pulmonary edema and ARDS
16. Pulmonary embolus
17. Chest tube ≥3 days post surgery

RENAL

18. Renal failure requiring dialysis

PROCEDURAL

19. Re-operation for bleeding
20. Wound dehiscence
21. Mediastinitis
22. Superficial wound infection
23. Post thoracotomy syndrome
24. Abrupt closure (regardless of previous dilation)
25. Vascular event requiring surgery
26. Event other than hemorrhage requiring transfusion
27. Coronary embolus
28. Coronary perforation
29. Sepsis
30. In-stent thrombosis (non-drug eluting stent)
31. In-stent thrombosis (drug eluting stent)

*A suspected MI is any episode of chest pain lasting longer than 20 minutes and not relieved by nitroglycerine and/or a development of new Q-waves, and/or other evidence of MI.

PROCEDURAL EVENTS

16.What was the condition of the patient upon leaving Cath Lab?

Stable 1( )

Unstable 2( )

Deceased 3( ) → Complete Mortality Checklist (DC) and question 18 below **only**

17. As of the end of this procedure, did the PCI operator plan to attempt an additional procedure within 2 weeks?

No 0( )

Yes 1( )

18. Did untoward event(s) occur in the Cath Lab?

No 0( )

Yes 1( ) →

18.1 List event(s) in temporal order using event codes.

_____,_____,_____,_____,_____

18.2 Other event(s) not listed.

No 0( )

Yes 1( ) → 18.2.1 Specify:_____

19. Did untoward event(s) occur within hospitalization after the patient left Cath Lab*?

No 0( )

Yes 1( ) →

19.1 Did abrupt closure occur out of lab?

No 0( )

Yes 1( ) → 19.1.1 Segment number code:___,___,___

19.2 List other event(s) in temporal order using event codes.

____,____,____,____

19.3 Other event(s) not listed.

No 0( )

Yes 1( ) → 19.3.1 Specify_____

*Report events occurring within hospitalization of this procedure. Any events occurring during or after a subsequent revascularization procedure should be reported on the procedure form for the subsequent procedure.

……...

Name code of person completing form___ ___ ___ ___ ___

Date of form completion ____/_____/____

mm dd yyyy

CANADIAN CARDIOVASCULAR SOCIETY CLASSIFICATION

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

II Slight limitation of ordinary activity. Walking or climbing stairs rapidly, walking uphill, walking or stair climbing after meals, in cold, in wind, or when under emotional stress or during the first few hours after awakening may cause pain. 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 1-2 blocks on a level and climbing one flight at normal conditions results in angina.

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

Date Entered _____
Initials_____

BARI 2D RESTING ECG LOG

BARI 2D ID__ __ __ __ __ __ __ __ __ __ __

Patient Name_____

MATRIX System will assign Resting ECG LOG ID ___ ___ ___ ___ ___ ___ ___ ___ ___ ___

1. Resting ECG Category (**Check all that apply**):

1.1 Pre-Revascularization

No 0 ( )
Yes 1( ) → 1.1.1 Date/ time of Revascularization:
____/____/_____ _____:_____ (use military time)
mm dd yyyy hh mm

1.2 Post-Revascularization

No 0 ( )
Yes 1( ) → 1.2.1 Date/ time of Revascularization:
____/____/_____ _____:_____ (use military time)
mm dd yyyy hh mm

1.3 Suspected MI

No 0 ( )
Yes 1( ) → 1.3.1 Date/ time of Suspected MI:
____/____/_____ _____:_____ (use military time)
mm dd yyyy hh mm

1.4 Scheduled Protocol Visit

No 0 ( )
Yes 1( ) → 1.4.1 Follow-up Period:

Baseline	1( )
3 Month	2( )
1 Year	3( )
2 Year	4( )
3 Year	5( )
4 Year	6( )
5 Year	7( )
6 Year	8( )
7 Year	9( )

1.5 Death

No 0 ( )
Yes 1( ) → 1.5.1 Date of Death:
____/____/_____
mm dd yyyy

2. Resting ECG available to send to CEL

No 0 ( ) ⟶

2.1 Reason Not Available:
- Patient Refused 1( )
- Patient Died 2( )
- Physician Refused 3( )
- Other 4( )
  - Specify: _____

Yes 1( ) ⟶

2.2 Date/ time of first ECG:
____/____/_____ _____:_____ (use military time)
mm dd yyyy hh mm

……

Name code of person completing form___ ___ ___ ___ ___

Date of form completion ____/_____/____
mm dd yyyy

BARI 2D RANDOMIZATION WORKSHEET

BARI 2D ID__ __ __ __ __ __ __ __ __ __ __

Patient Name_____ Date of Randomization:_____/_____/_____
mm dd yyyy

PRIMARY EXCLUSION CRITERIA

1. Definite need for invasive intervention as determined by the attending cardiologist	No 0( ) Yes 1( )
2. Prior bypass surgery (CABG) or prior catheter-based intervention within the past 12 months	No 0( ) Yes 1( )
3. Planned intervention for disease in bypass graft(s) if the patient is randomized to a strategy of initial revascularization	No 0( ) Yes 1( )
4. Class III or IV CHF	No 0( ) Yes 1( )
5. Creatinine >2.0 mg/dl (181.9 µmol/L)	No 0( ) Yes 1( )
6. HbAlc >13%	No 0( ) Yes 1( )
7. Need for major vascular surgery concomitant with revascularization (e.g., carotid endarterectomy)	No 0( ) Yes 1( )
8. Left main stenosis $\geq$50%*	No 0( ) Yes 1( )
9. Noncardiac illness expected to limit survival	No 0( ) Yes 1( )
10. Hepatic disease (ALT >2 times the ULN)	No 0( ) Yes 1( )
11. Fasting triglycerides > 1000 mg/dl (11.3 mmol/L) in the presence of moderate glycemic control (HbAlc < 9.0%)	No 0( ) Yes 1( )
12. Current alcohol abuse	No 0( ) Yes 1( )
13. Chronic steroid use judged to interfere with the control of diabetes, exceeding 10 mg of Prednisone per day or the equivalent	No 0( ) Yes 1( )
14. Pregnancy known, suspected, or planned in next 5 years	No 0( ) Yes 1( )
15. Geographically inaccessible or unable to return for follow-up	No 0( ) Yes 1( )
16. Enrolled in a competing randomized trial or clinical study	No 0( ) Yes 1( )
17. Unable to understand or cooperate with protocol requirements	No 0( ) Yes 1( )

*Patients with this characteristic were found to benefit from CABG compared to medical therapy in randomized clinical trials.

PRIMARY INCLUSION CRITERIA

1. Diagnosis of Type 2 diabetes mellitus	No 0( ) Yes 1( )
2. Coronary arteriogram showing one or more vessels amenable to revascularization (≥50% stenosis)	No 0( ) Yes 1( )
3. Objective documentation of ischemia OR subjectively documented typical angina with ≥70% stenosis in at least one artery	No 0( ) Yes 1( )
4. Suitability for coronary revascularization by at least one of the available methods (does not require the ability to achieve complete revascularization)	No 0( ) Yes 1( )
5. Ability to perform all tasks related to glycemic control and risk factor management	No 0( ) Yes 1( )
6. Age 25 or older	No 0( ) Yes 1( )
7. Informed written consent	No 0( ) Yes 1( )

ADDITIONAL WRITTEN CONSENTS

1. Signed consent for Economics study	No 0( ) Yes 1( )
2. Signed consent for Genetics study	No 0( ) Yes 1( )

RANDOMIZATION

1. Select preferred revascularization method.

CABG	1( )
PCI	2( )

2. Record Patient BARI 2D ID: __ __ __ __ __ __ __ __ __ __ __ __

3. Record Patient BARI 2D Screening ID: __ __ __ __ __ __ __ __ __ __

……

Name code of person completing form ___ ___ ___ ___ ___

Date of form completion ____/____/____
mm dd yyyy

Form not entered into MATRIX -
Variable names not required

BARI 2D SERIOUS ADVERSE EVENT FORM

BARI 2D ID__ __ __ __ __ __ __ __ __ __ __

TO BE COMPLETED WITHIN 48 HOURS UPON NOTIFICATION OF EVENT AND FAXED TO COORDINATING CENTER AT 412-383-8690

Section A. Does this form need to be completed? Answer all four questions below.

1. Was the event a death?
   No 0 ( ) Yes 1 ( )

2. Was the patient on combination therapy of Rosiglitazone and Insulin at the time of the serious event?
   No 0 ( ) Yes 1 ( )

3. Was the patient on combination therapy of Avandamet and Insulin at the time of the serious event?
   No 0 ( ) Yes 1 ( )

4. In the opinion of the Principal Investigator, was there a **causal relationship** between the research intervention and the serious event (i.e., is there a reasonable possibility that the event may have been caused by the intervention) and was the serious event **unexpected** (i.e., not identified in nature, severity or frequency in the current IRB approved research protocol or informed consent document)?
   No 0 ( ) Possible 1 ( ) Probable 2 ( ) Definite 3 ( ) Unknown -3 ( )

If you answered "No" to questions 1, 2, 3, and 4, STOP HERE. You do not need to submit an SAE form. Otherwise proceed to Section B.

……

Section B.

5. Date of event onset: _____/_____/_____
   mm dd yyyy

6. Explanation of Event (EXPLANATION REQUIRED; attach additional paper if necessary):

   _____

   _____

   _____

   _____

   _____

7. Which study intervention is the event thought to be related to:
   Diabetes 0 ( ) Revascularization 1 ( ) Both 2 ( ) Neither 3 ( )

8. Was the local IRB notified of the adverse event?
   No 0 ( ) Yes 1 ( ) → Date notified_____/_____/_____
   mm dd yyyy

Important: You must attach a copy of the FDA Medwatch form and any related documentation submitted to the local IRB to this form.

……..

Date of form completion: _____/_____/_____
mm dd yyyy

Name code of person completing form __ __ __ __ __

SERIOUS ADVERSE EVENT FORM INSTRUCTIONS

SECTION A. DETERMINATION OF WHETHER THE FORM NEEDS TO BE COMPLETED

1. **WAS THE EVENT A DEATH**: Record whether or not adverse event ended in death.

2. **WAS THE PATIENT ON COMBINATION THERAPY OF ROSIGLITAZONE AND INSULIN AT THE TIME OF THE EVENT**: Record whether or not patient was on combination therapy of rosiglitazone and insulin at time of event.

3. **WAS THE PATIENT ON COMBINATION THERAPY OF AVANDAMET AND INSULIN AT THE TIME OF THE EVENT**: Record whether or not patient was on combination therapy of avandamet and insulin at time of event.

4. **IN THE OPINION OF THE PRINCIPAL INVESTIGATOR, WAS THERE A CAUSAL RELATIONSHIP BETWEEN THE INTERVENTION AND THE EVENT**: Record whether or not the PI feels there was a casual relationship between the intervention and the event.
    - **CAUSAL RELATIONSHIP:** defined as a reasonable possibility that the event may have been caused by the intervention
    - **UNEXPECTED:** defined as not identified in nature, severity or frequency in the current IRB approved research protocol or informed consent document.

If questions 1, 2, 3, and 4 are all checked "No", STOP. The SAE form does not need to be completed. If "Yes" or "Unknown" are checked for any of the four questions, proceed to Section B.

SECTION B. DETAILS OF EVENT

5. **DATE OF EVENT ONSET:** Record date of death or event onset.

6. **EXPLANATION OF EVENT**: An explanation of the event is required and should include enough information about the event to allow the Coordinating Center and others to whom the event is reported (IRB, NIH, FDA, etc.) to determine if a possible link exists between the event and BARI 2D. If a medication is linked to the event, include the name of the medication in the explanation. Attach additional paper if necessary. **Do not include patient name, randomization assignment or any other patient identifying information.**

7. **WHICH STUDY INTERVENTION IS THE EVENT THOUGHT TO BE RELATED TO**: Indicate if the event is thought to be related to the diabetes intervention, revascularization intervention, both interventions, or neither intervention.

8. **IRB NOTIFICATION**: Record whether or not the local IRB was notified of the event and the date of notification. The local IRB must be notified for each death. Send a copy of any related documentation submitted to the local IRB.

BARI 2D SEVERE HYPOGLYCEMIA FORM

Date Entered_____
Initials_____

Date Verified_____
Initials_____

BARI 2D ID__ __ __ __ __ __ __ __ __ __ __ __

Patient Name_____

Please complete this form for each severe hypoglycemia episode (according to the definition below) and enter into MATRIX within a week after learning of the episode.

Definition of Severe Hypoglycemia Episode: An event characterized by patient's inability to self-treat and one of the following two conditions: (i) blood glucose <50 mg/dl determined in a health care facility or a finger stick reading determined by non-medical or EMS personnel, or (ii) confusion, irrational or uncontrollable behavior, convulsions, or coma reversed by treatment that raises blood glucose.

SECTION A: RECOGNITION OF EPISODE

1. Specify date of onset of the episode: ____/____/____
   mm dd yyyy

2. Specify time of onset of the episode: ____ :____ (use military time)
   hh mm

3. Specify date when the BARI 2D personnel learned of the episode: ____/____/____
   mm dd yyyy

4. How did the clinic learn of the episode? (Check one)

Patient contacted clinic	1 ( )
Patient's family/friends contacted clinic	2 ( )
Third party contacted clinic	3 ( )
Clinic recognized event and informed the patient	4 ( )
Patient informed clinic at follow-up visit	5 ( )
Other	6 ( )

Specify: _____

5. Record when onset of hypoglycemia occurred:

While patient was asleep	1 ( )
While patient was awake	2 ( )
Unknown	-3 ( )

SECTION B: CLINICAL MANIFESTATION

1. Indicate all symptoms or signs that occurred. Check all that apply:

		No	Yes	Unknown
1.1	Loss of consciousness	0( )	1( )	-3( )
1.2	Seizure	0( )	1( )	-3( )
1.3	Suspected seizure	0( )	1( )	-3( )
1.4	Unusual difficulty in awakening	0( )	1( )	-3( )
1.5	Irrational or uncontrollable behavior	0( )	1( )	-3( )
1.6	Confusion	0( )	1( )	-3( )
1.7	Memory loss	0( )	1( )	-3( )

SECTION C: BLOOD GLUCOSE DETERMINATION

1. Was the blood glucose measured **BEFORE** treatment (if the episode was not treated, was the blood glucose measured **AT ALL**)?

No 0 ( )
Yes 1 ( ) →
Unknown -3 ( )

1.1 By whom:
- Patient 1 ( )
- Medical care personnel 2 ( )
- Other 3 ( )
- Specify: _____

1.2 How long after the episode onset was blood glucose measured? Hour(s) _____ Minutes _____
hh mm

1.3 Record measurement: _____ _____ _____mg/dl
_____ _____ _____mmol/L

1.4 Method used:
- Blood glucose monitor 1 ( )
- Lab determination (Plasma) 2 ( )

SECTION C: BLOOD GLUCOSE DETERMINATION

2. Was the blood glucose measured **AFTER** treatment (Check "No" if episode was not treated)?

No 0 ( )
Yes 1 ( ) →
Unknown -3 ( )

2.1	By whom:	
	Patient	0 ( )
	Medical care personnel	1 ( )
	Other	2 ( )
	Specify: _____	
2.2	How long after treatment was blood glucose measured? Hour(s) _____ (hh) Minutes _____ (mm)	
2.3	Record measurement: _____ _____ _____mg/dl _____ _____ _____mmol/L	
2.4	Method used:	
	Blood glucose monitor	1 ( )
	Lab determination (Plasma)	2 ( )

SECTION D: TREATMENT OF CLINICAL MANIFESTATION

1. Was treatment administered? No 0 ( ) Yes 1 ( ) →

1.1 How long after the onset of the episode was treatment started?
Hour(s) _____ (hh) Minutes _____ (mm)

Record treatment administered:		No	Yes	Unknown
1.2	Intravenous glucose	0 ( )	1 ( )	-3 ( )
1.3	Glucagon	0 ( )	1 ( )	-3 ( )
1.4	Oral carbohydrates	0 ( )	1 ( )	-3 ( )
1.5	Other	0 ( )	1 ( )	-3 ( )
	Specify: _____			

SECTION D: TREATMENT OF CLINICAL MANIFESTATION

		No	Yes	Unknown
2.	Did the symptoms reverse without/before treatment?	0 ( )	1 ( )	-3 ( )
3.	Did the patient treat SELF?	0 ( )	1 ( )	-3 ( )
4.	Did the patient receive assistance?	0 ( )	1 ( )	-3 ( )
5.	Was the patient hospitalized or treated in an emergency room or other medical facility?	0 ( )	1 ( )	-3 ( )

SECTION E: ASSOCIATED EVENTS

1. Was the hypoglycemia episode associated with:

		No	Yes	Unknown
1.1	Recent changes in diabetes medications or doses	0( )	1( )	-3( )
1.2	Missed meal or snack	0( )	1( )	-3( )
1.3	Exercise	0( )	1( )	-3( )
1.4	Alcohol use	0( )	1( )	-3( )
1.5	Change in beta-blocker, or increased dose	0( )	1( )	-3( )
1.6	Medication dosage error	0( )	1( )	-3( )

2. Did any of the following occur with the hypoglycemia episode?

No 0 ( )
Yes 1 ( ) →

Check all that apply:		No	Yes
2.1	Death	0( )	1( )
2.2	Neurological insult requiring hospitalization	0( )	1( )
2.3	Myocardial infarction	0( )	1( )
2.4	Stroke	0( )	1( )
2.5	Injury to the patient requiring hospitalization	0( )	1( )
2.6	Injury to another person	0( )	1( )
2.7	Property damage	0( )	1( )
2.8	Traffic violation	0( )	1( )
2.9	Patient missed days at work	0( )	1( )

2.9.1 Number of work days missed: _____

SECTION F: TREATMENT REGIMEN PATIENT WAS ON AT THE TIME OF THE EPISODE

1. Record diabetes medications:

		No	Yes	Drug Code	Total Daily Dose
1.1	Biguanide	0( )	1( )	_____	_____mg
1.2	Thiazolidinedione	0( )	1( )	_____	_____mg
1.3	Sulfonylurea	0( )	1( )	_____	_____mg
1.4	Meglitinide	0( )	1( )	_____	_____mg
1.5	Phenylalanine Derivative	0( )	1( )	_____	_____mg
1.6	Alpha Glucosidase Inhibitor	0( )	1( )	_____	_____mg
1.7	Prolonged Acting Insulin*	0( )	1( )	_____	_____units
				_____	_____units
1.8	Short Acting Insulin**	0( )	1( )	_____	_____units
				_____	_____units
1.9	Insulin Pump	0( )	1( )	_____	_____units

1.9.1 If a pump patient, is a pump malfunction suspected?

No 0 ( )
Yes 1 ( )
Unknown -3 ( )

1.10	Other	0( )	1( )	_____	_____mg

Specify _____

*** Prolonged Acting Insulin should include: NPH, Lente, Ultralente, Glargine, 80/20, 75/25, 70/30 and 50/50**

****Short Acting Insulin should include: Regular, Lispro, and Aspart**

SECTION F: TREATMENT REGIMEN PATIENT WAS ON AT THE TIME OF THE EPISODE

2. Record other medications:

	Drug Name (Generic)	Drug Code (if applicable)	Total Daily Dose	Check appropriate unit		
				mg	other	(specify)
2.1	_____	_____	_____	1 ( )	2 ( )	_____
2.2	_____	_____	_____	1 ( )	2 ( )	_____
2.3	_____	_____	_____	1 ( )	2 ( )	_____
2.4	_____	_____	_____	1 ( )	2 ( )	_____
2.5	_____	_____	_____	1 ( )	2 ( )	_____
2.6	_____	_____	_____	1 ( )	2 ( )	_____
2.7	_____	_____	_____	1 ( )	2 ( )	_____
2.8	_____	_____	_____	1 ( )	2 ( )	_____
2.9	_____	_____	_____	1 ( )	2 ( )	_____
2.10	_____	_____	_____	1 ( )	2 ( )	_____

SECTION G: COMMENTS (Optional)

Use this for space for any relevant comments (e.g., clarifications, additional information, etc):

_____

_____

_____

_____

_____

_____

……

Name code of person completing form ___ ___ ___ ___ ___

Date of form completion____/____/____
mm dd yyyy

BARI 2D SURGERY PROCEDURE FORM

Date Entered _____
Initials_____

Date Verified_____
Initials_____

BARI 2D ID__ __ __ __ __ __ __ __ __ __ __ __

Patient Name_____

---

1. Date of Surgery: ____/____/____
   mm dd yyyy

2. Approximate procedure start time____:_____(use military time)
   hh mm

3. Category of surgery:

   Assigned BARI 2D Revascularization 1( )
   Other 2( ) →

Primary reason for revascularization: (**Check all that apply**)

	No	Yes
3.1 Acute coronary syndrome/acute event	0( )	1( )
3.2 Severe symptoms	0( )	1( )
3.3 Worsened ischemia	0( )	1( )
3.4 Unsatisfactory results of recent intervention	0( )	1( )
3.5 Objective evidence of CAD progression	0( )	1( )
3.6 Other	0( )	1( )

Specify: _____

4. BARI 2D Surgeon I.D.__ __ __ __ (enter 0000 if non-BARI 2D surgeon)

5. Revascularization priority:

   Elective 1( )
   Urgent 2( )
   Emergency 3( )

6. Patient's anginal status at time of surgery:

   Stable 1( ) →
   Unstable 2( )
   Acute MI 3( )

6.1 Record Canadian Cardiovascular Society Classification:
I( ) II( ) III( ) IV( )

7. Therapy Pre-Procedure (within 48 hours):

		No	Yes
7.1	Beta Blocker	0 ( )	1( )
7.2	Calcium Channel Blocker (verapamil, diltiazem)	0 ( )	1( )
7.3	Calcium Channel Blocker (all others)	0 ( )	1( )
7.4	Nonsublingual Nitrate	0 ( )	1( )
7.5	Sublingual Nitrates or Nitro spray	0 ( )	1( )
7.6	IV Nitroglycerin	0 ( )	1( )
7.7	Antiarrhythmic agent	0 ( )	1( )
7.8	Diuretic	0 ( )	1( )
7.9	ACE Inhibitor	0 ( )	1( )
7.10	Angiotensin Receptor Blocker	0 ( )	1( )
7.11	Vasodilator (other than the above)	0 ( )	1( )
7.12	Digitalis or derivative	0 ( )	1( )
7.13	Inotropic agent	0 ( )	1( )
7.14	Alpha Blocker	0 ( )	1( )
7.15	Aspirin	0 ( )	1( )
7.16	Ticlopidine/Clopidogrel	0 ( )	1( )
7.17	Antiplatelet agent other than ticlopidine, clopidogrel (includes persantine/sulfinpyrazone)	0 ( )	1( )
7.18	Heparin (includes low molecular weight heparin)	0 ( )	1( )
7.19	Warfarin	0 ( )	1( )
7.20	Thrombolytic therapy	0 ( )	1( )
7.21	IIb/IIIa Receptor Antagonist	0 ( )	1( )
7.22	Lipid lowering agent	0 ( )	1( )
7.23	Intra Aortic Balloon Pump	0 ( )	1( )
7.24	Insulin	0 ( )	1( )
7.25	Aldosterone Receptor Antagonist	0 ( )	1( )

PERI-PROCEDURAL INFORMATION

8. Type of Procedure:

Full sternotomy	1( )
Partial sternotomy	2( )
Lateral thoracotomy	3( )

9. Was the procedure performed off-pump (i.e. without cardiopulmonary bypass support)?

No 0 ( )

Yes 1 ( )

9.1 Primary method of myocardial protection:	(Check only one)	
Intermittent cross-clamp		1 ( )
Blood cardioplegia		2 ( )
Crystalloid cardioplegia		3 ( )
O2 crystalloid cardioplegia		4 ( )
Continuous perfusion/No cross-clamp		5 ( )
9.2 Was retrograde perfusion used?	No	0 ( )
	Yes	1 ( )
9.3 Was topical hypothermia used?	No	0 ( )
	Yes	1 ( )

9.4 Lowest core temperature _____° C

9.5 Duration of cardiopulmonary bypass _____minutes

9.6 Duration of cross-clamp_____minutes

10. Glucose control during procedure:

10.1 Number of glucose measurements: _____

10.2 Highest glucose recorded: _____mg/dl _____mmol/L

10.3 Method of insulin administration:

	No	Yes	Maximum Dose
10.3.1 Subcutaneous	0 ( )	1( )	_____Units
10.3.2 Intravenous	0 ( )	1( )	_____Units
10.3.3 Continuous IV drip	0 ( )	1( )	_____Units/hour

PERI-PROCEDURAL INFORMATION

11. Total number of distal anastomotic sites _____

12. Total number of conduits_____

			CONDUIT NUMBER					
			1	2	3	4	5	6
12.1	Distal Anastomoses (refer to diagram on page 3a)	A:	___	___	___	___	___	___
		B:	___	___	___	___	___	___
		C:	___	___	___	___	___	___
		D:	___	___	___	___	___	___
		E:	___	___	___	___	___	___
12.2	Configuration (1=End to Side, 2= Side to Side)	A:	___	___	___	___	___	___
		B	___	___	___	___	___	___
		C:	___	___	___	___	___	___
		D:	___	___	___	___	___	___
		E:	___	___	___	___	___	___
12.3	Check if Y-graft		( )	( )	( )	( )	( )	( )
12.4	Conduit material[1] (refer to codes on page 3b)		___	___	___	___	___	___
12.5	Conduit flow (1 = Inadequate, 2 = Questionable, 3 = Adequate)		___	___	___	___	___	___
12.6	Approximate conduit diameter (mm)		__.__	__.__	__.__	__.__	__.__	__.__
12.7	Distal Vessel Quality[2] (refer to codes on page 3b)	A:	___	___	___	___	___	___
		B:	___	___	___	___	___	___
		C:	___	___	___	___	___	___
		D:	___	___	___	___	___	___
		E:	___	___	___	___	___	___
12.8	Estimated Distal Vessel Diameter (mm)	A:	__.__	__.__	__.__	__.__	__.__	__.__
		B:	__.__	__.__	__.__	__.__	__.__	__.__
		C:	__.__	__.__	__.__	__.__	__.__	__.__
		D:	__.__	__.__	__.__	__.__	__.__	__.__
		E:	__.__	__.__	__.__	__.__	__.__	__.__

PERI-PROCEDURAL INFORMATION

13. If more than 6 conduits were used, or a graft had more than 5 distal anastomoses, describe:

_____

_____

14. Any intended vessels (according to surgeon's initial treatment plan) not grafted?

No 0 ( )
Yes 1 ( ) →

	Intended vessel(s) not grafted				
	1	2	3	4	5
14.1 Distal site code[1]	___	___	___	___	___
(check all reasons that apply)					
14.2 Too small	___	___	___	___	___
14.3 Diseased	___	___	___	___	___
14.4 Inaccessible	___	___	___	___	___
14.5 Cannot find	___	___	___	___	___
14.6 Inadequate Conduit	___	___	___	___	___
14.7 Akinetic Segment	___	___	___	___	___
14.8 Other	___	___	___	___	___
Specify: _____					

[1]Record site from BARI 2D coronary tree diagram.

POST PROCEDURAL INFORMATION

15. Condition of patient upon leaving operating room:

Stable 1 ( )
Unstable 2 ( )
Deceased 3 ( ) →

Complete Mortality Checklist (DC) and question #17 **only.**

16. Record post-bypass pharmacologic/mechanical support:

		No	Yes
16.1	Inotropic agents >48 hours	0 ( )	1( )
16.2	New permanent pacemaker	0 ( )	1( )
16.3	Left ventricular assist device	0 ( )	1( )
16.4	Right ventricular assist device	0 ( )	1( )
16.5	Intra Aortic balloon pump	0 ( )	1( )

POST PROCEDURAL INFORMATION

17. Did untoward event(s) occur in the operating room?

No 0( )
Yes 1( ) →

17.1 List event(s) in temporal order using event codes.

____,____,____,____,____

17.2 Other event(s) not listed.

No 0( )
Yes 1( ) → 17.2.1 Specify:_____

18. Did untoward event(s) occur within hospitalization after patient left operating room?*

No 0( )
Yes 1( ) →

18.1 List event(s) in temporal order using event codes.

____,____,____,____,_____

18.2 Other event(s) not listed.

No 0( )
Yes 1( ) → 18.2.1 Specify:_____

19. Glucose control 24 hours post procedure:

19.1 Number of glucose measurements: _____

19.2 Highest glucose recorded:_____mg/dl _____mmol/L

19.3 Method of insulin administration:

	No	Yes	Maximum Dose
19.3.1 Subcutaneous	0 ( )	1( )	_____Units
19.3.2 Intravenous	0 ( )	1( )	_____Units
19.3.3 Continuous IV drip	0 ( )	1( )	_____Units/hour

* Report events occurring within hospitalization of this procedure. Any events occurring during or after a subsequent revascularization procedure should be reported on the procedure form for the subsequent procedure.

……

Name code of person completing form___ ___ ___ ___ ___

Date of form completion ____/_____/____
mm dd yyyy

LIST OF EVENTS

EVENTS

1. Nonfatal cardiac arrest requiring CPR or countershock
2. Suspected MI* → Fill out Suspected MI Checklist (MIL)
3. Congestive Heart Failure (isolated)
4. Pulmonary Edema (cardiac)
5. Cardiogenic shock
6. Cardiac tamponade
7. Hemorrhage requiring transfusion
8. Hypersensitivity reaction
9. Hypotension requiring treatment

NEUROLOGIC

10. Transient cerebrovascular event, 24 hours or less
11. Cerebrovascular accident (stroke) → Fill out CVA Form
12. Dementia
13. Coma

VASCULAR

14. Arterial embolus of extremity or loss of pulse requiring treatment

PULMONARY

15. Respiratory failure including non-cardiac pulmonary edema and ARDS
16. Pulmonary embolus
17. Chest tube ≥3 days post surgery

RENAL

18. Renal failure requiring dialysis

PROCEDURAL

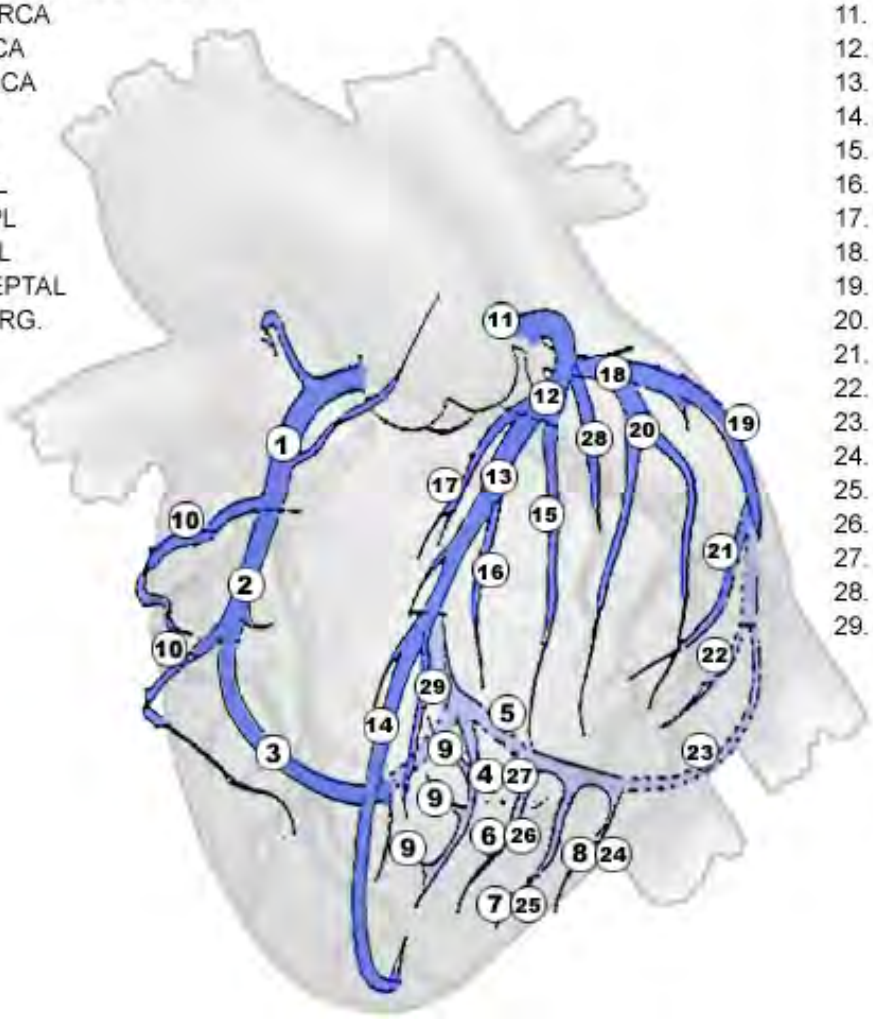
19. Re-operation for bleeding
20. Wound dehiscence
21. Mediastinitis
22. Superficial wound infection
23. Post thoracotomy syndrome
24. Abrupt closure (regardless of previous dilation)
25. Vascular event requiring surgery
26. Event other than hemorrhage requiring transfusion
27. Coronary embolus
28. Coronary perforation
29. Sepsis
30. In-stent thrombosis (non-drug eluting stent)
31. In-stent thrombosis (drug eluting stent)

*A suspected MI is any episode of chest pain lasting longer than 20 minutes and not relieved by nitroglycerine and/or a development of new Q-waves, and/or other evidence of MI.

BARI 2D CORONARY TREE DIAGRAM

RIGHT CORONARY ARTERY

1. PROX RCA
2. MID RCA
3. DIST RCA
4. RPDA
5. RPAV
6. 1st RPL
7. 2nd RPL
8. 3rd RPL
9. INF. SEPTAL
10. AC MARG.



LEFT CORONARY ARTERY

11. LMCA
12. PROX LAD
13. MID LAD
14. DIST LAD
15. 1st DIAG
16. 2nd DIAG
17. 1st SEPTAL
18. PROX CX
19. MID CX
20. 1st OB MARG
21. 2nd OB MARG
22. 3rd OB MARG
23. LAV
24. 1st LPL
25. 2nd LPL
26. 3rd LPL
27. LPDA
28. RAMUS
29. 3rd DIAG

[1]BARI 2D Conduit Material Codes

	Code	Conduit
Artery	01	LIMA
	02	RIMA
	03	Free LIMA
	04	Free RIMA
	05	Gastroepiploic
	06	Radial
	07	Other Artery
Vein	11	Thigh SVG
	12	Leg SVG
	13	Lesser SVG
	14	Arm
	15	Other Vein

[2]BARI 2D Distal Vessel Quality Codes

1. Normal
2. Mild, diffuse, intimal thickening or plaque formation
3. Moderate diffuse, intimal thickening or plaque formation w/some luminal compromise
4. Severe, diffuse, intimal thickening with significant luminal compromise
5. Endarterectomy performed

BARI NUCLEAR CORE LAB
University of Alabama at Birmingham
LHRB 314
701 South 19th Street
Birmingham, AL 35294-0007

BARI-2D Transfer Image Acquisition DATA to be filled at site

Fax to 1-800-513-0656

ID number: _____ **Date of Study:** _____

Name Code: _____ **Date received*:** _____

Site:_____ **Height:**____ **Weight:**____

Date of Randomization:_____ **Age:**_____ **Sex:**_____

Scheduled Test (Year 1, 2, 3, 4, 5, 6):_____
Unscheduled Test: Date_____

Please check the appropriate response.

1. TYPE OF STRESS ☐ 1. ADENOSINE ☐ 2. DIPRYDAMOLE **[CANADIAN SITES ONLY]**
___Alone
___With Handgrip Exercise
___With Treadmill Exercise

2. TRACER (Stress/Rest): ☐ 1. MIBI/MIBI ☐ 2. MIBI/thallium (dual isotope)

3. PROTOCOL: ☐ 1. Stress-Rest,1-day ☐ 2. Rest-Stress,1-day
☐ 3. Stress-rest, 2-day

4. ACQUISITION: ☐ 1. 180 deg. ☐ 2. 360 deg.

5. DOSE MIBI/MIBI: Rest _____ mCi Stress_____ mCi

6. DOSE (Dual Isotope): MIBI _____ mCi Thallium _____ mCi

Was the study performed according to protocol: YES ☐ ***NO*** ☐

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Birmingham, AL 35294-0007

BARI - 2D: SPECT Transfer Data

ID number:_____

Name Code:_____

Date of Study:_____

Date send:_____

Site:_____

Adenosine or Diprydamole SPECT Perfusion Imaging

	Perfusion			
	Normal	Reversible	Partially reversible	Fixed
1- Anterior wall	☐	☐	☐	☐
2. Septum	☐	☐	☐	☐
3. Inferior wall	☐	☐	☐	☐
4. Lateral wall	☐	☐	☐	☐
5. Apex	☐	☐	☐	☐

LVEF: 1-Post Stress: _____ % 2-Rest:_____ %

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Birmingham, AL 35294-0007

BARI - 2D: Transfer data

ID Number: _____

Name Code:_____

Site **:** _____

Date of Study:_____

Date received_____

Response to Adenosine or Diprydamole Infusion

I. Heart Rate:

a) Rest = _____bpm
b) Stress= _____bpm

II. Blood Pressure:

a) Rest = _____mmHg
b) Stress= _____mmHg

III Resting ECG:

☐ a) Normal
☐ b) NS ST/T
☐ c) AFIB
☐ d) ANT MI
☐ e) INF MI
☐ f) ANT MI/I MI
☐ g) LVH
☐ h)Pace-maker
☐ I) LBBB
☐ j) Other

IV. Chest Pain:

☐ a) Yes
☐ b) No

V. Ischemic ST Response:

☐ a) Yes
☐ b) No
☐ c) Non- Diagnostic