Post Op AFIB

CASE REPORT FORMS

Patient ID: ☐☐-☐☐☐

1.	Date of Birth:	☐☐/☐☐☐/☐☐☐☐ d d m m m y y y y
2.	Sex:	O Male O Female
3.	Ethnic Category:	O Hispanic or Latino O Not Hispanic or Latino
4.	Racial Category *(check one):* O American Indian or Alaska Native O Asian O Black or African American O Native Hawaiian or Other Pacific Islander O White	
5.	Payor *(check all that apply)*: ☐ Medicaid ☐ Medicare ☐ Other Government ☐ Private ☐ None/Self Payor	

Patient ID: ☐☐-☐☐☐

Cardiovascular/Vascular		
1. Previous Myocardial Infarction		O No O Yes
2. Myocarditis		O No O Yes
3. Cardiomyopathy		O No O Yes
4. Heart Failure		O No O Yes
5. Rheumatic Heart Disease		O No O Yes
6. Non Rheumatic Valve Disease		O No O Yes
7. History of arrhythmia (Not AF or AFL)		O No O Yes
8. Hypertension		O No O Yes
9. PVD		O No O Yes
Cardiac Procedures		
10. Prior Revascularization		O No O Yes
11. Pacemaker		O No O Yes
12. ICD		O No O Yes
Neurological		
13. Neurological disorder (other than stroke)		O No O Yes
14. History of Stroke		O No O Yes
Pulmonary		
15. Pulmonary Hypertension		O No O Yes
16. COPD		O No O Yes
Metabolic/Endocrine		
17. Hyperthyroidism		O No O Yes
18. Hypothyroidism		O No O Yes
19. Diabetes		O No O Yes
	Type:	O Insulin Dependent O Non-Insulin Dependent
Other		
20. Sleep Apnea		O No O Yes
	Treatment: *(check all that apply)*	☐ None ☐ Bipap ☐ Surgery ☐ Other

Anthropometrics	
21. Height	☐☐☐.☐cm
22. Weight	☐☐☐.☐ kg

LVEF	
23. LVEF	☐☐%

Left Atrial Volume Index	
24. Left Atrial Volume Index	☐☐.☐ ml/m^2

Patient ID: ☐☐-☐☐☐

1.	Digoxin	O No	O Yes
2.	Nitrate	O No	O Yes
3.	Diuretic	O No	O Yes
4.	Beta Blocker	O No	O Yes
5.	Aldosterone Receptor Antagonist (e.g. Spironolactone)	O No	O Yes
6.	Angiotensin Converting Enzyme Inhibitor (ACEi)	O No	O Yes
7.	Angiotensin II Antagonist (ARB)	O No	O Yes
8.	Calcium Channel Blocker	O No	O Yes
9.	Inotropic or vasoactive therapy	O No	O Yes

Patient ID: ☐☐-☐☐☐ **Procedure Date:** ☐☐/☐☐☐/☐☐☐☐ (d d m m m y y y y)

SURGICAL PROCEDURE

1. Specify primary procedure performed:

O CABG only
O Valve Repair only
O CABG and Valve Repair
O Valve Replacement only *(specify):*

☐ TV Type of replacement valve: O Bioprosthetic O Mechanical
☐ MV Type of replacement valve: O Bioprosthetic O Mechanical
☐ AV Type of replacement valve: O Bioprosthetic O Mechanical

O CABG and Valve Replacement *(specify):*

☐ TV Type of replacement valve: O Bioprosthetic O Mechanical
☐ MV Type of replacement valve: O Bioprosthetic O Mechanical
☐ AV Type of replacement valve: O Bioprosthetic O Mechanical

OPERATIVE PARAMETERS

2. OR entry time: ☐☐:☐☐ (24 hour clock)
3. Robotic approach O No O Yes
4. CPB: O On pump O Off pump

CPB time: ☐☐☐ minutes
Did the aorta get cross clamped? O No O Yes
Aortic cross clamp time: ☐☐☐ minutes

5. Was chest closed in the OR? O No O Yes

Skin to Skin time ☐☐☐ minutes

CONCOMITANT PROCEDURES

6. Were any concomitant procedures performed? O No O Yes *(check all that apply)*

☐ Atrial Septal Defect repair
☐ Closure of PFO
☐ Intra-Aortic Balloon Placement
☐ ICD implant
☐ Permanent Pacemaker implant
☐ Other procedure

INTRAOPERATIVE MEDICATIONS

7. Specify intraoperative pharmacologic therapy administered to patient *(check all that apply)*

Activated factor VII	☐	Lidocaine	☐
Amicar	☐	Milrinone	☐
Amiodarone	☐	Nesiritide	☐
☐ IV Bolus # of boluses☐ ☐ IV Drip			
Aprotinin, dose: ☐ full ☐ half	☐	Nitroglycerin	☐
Dobutamine	☐	Nitroprusside	☐
Dopamine	☐	Norepinephrine	☐
Epinephrine	☐	Procainamide	☐
Heparin	☐	Protamine	☐
Inhaled Iloprost	☐	Sildenafil (Viagra)	☐
Inhaled Nitric Oxide	☐	Tranexamic acid (Cyklokapron)	☐
Inhaled Prostacyclin	☐	Vasopressin	☐
Isoproterenol	☐	Other ~~(specify)~~: _____	☐

INTRAOPERATIVE BLOOD TRANSFUSIONS

8. Specify blood products given intraoperatively and specify # units/ccs administered *(check all that apply)*

☐ None
☐ PRBCs: ☐☐.☐Units
☐ Platelets: ☐☐☐☐ Platelet Units: O Units O cc
☐ Fresh Frozen Plasma: ☐☐☐ FFP Units: O Units O cc
☐ Cryoprecipitate: ☐☐☐Units
☐ Cell Saver: ☐☐☐☐ cc

Patient ID: ☐☐-☐☐☐

1. Date of Randomization:	☐☐/☐☐☐/☐☐☐☐ d d m m m y y y y
2. Time of Randomization:	☐☐:☐☐ (24 hour clock) Time at Clinical Center

3. Randomization Assignment

☐ **Group 1: Rate Control** ☐ **Group 2: Rhythm Control**

_____
Signature

Patient ID: ☐☐-☐☐☐

1. Date of Hospital Admission:	☐☐/☐☐☐/☐☐☐☐ (d d m m m y y y y)

2. ICU Days (To be collected after the Index Surgery)

Event	Type	Entry Date	Entry Time (24 hour clock)	Discharge Date	Discharge time (24 hour clock)
1.	O ICU	☐☐/☐☐☐/☐☐☐☐ (d d m m m y y y y)	☐☐:☐☐	☐☐/☐☐☐/☐☐☐☐ (d d m m m y y y y)	☐☐:☐☐
2.	O ICU	☐☐/☐☐☐/☐☐☐☐ (d d m m m y y y y)	☐☐:☐☐	☐☐/☐☐☐/☐☐☐☐ (d d m m m y y y y)	☐☐:☐☐
3.	O ICU	☐☐/☐☐☐/☐☐☐☐ (d d m m m y y y y)	☐☐:☐☐	☐☐/☐☐☐/☐☐☐☐ (d d m m m y y y y)	☐☐:☐☐

Conversion to Sustained, Stable, Non- AF Rhythm

3. Did patient convert to sustained, stable non-AF rhythm within 7 days of randomization or by hospital discharge O No O Yes

Date of conversion ☐☐/☐☐☐/☐☐☐☐ (d d m m m y y y y)

Time of conversion ☐☐:☐☐

4.Rhythm/Rate Criteria

Specify based on treatment patient is receiving *(check one treatment)*

O **Rhythm Control** **(At least one criterion must be checked to qualify for cardiac discharge eligibility)**	O **Rate Control** **(Criterion below must be checked to qualify for cardiac discharge eligibility)**
☐ Absence of AF for 24 or more consecutive hours and no AF at time of discharge.	☐ Ventricular rate at rest should be <100 bpm
☐ Presence of AF after treatment with amiodarone for at least 48 hours (which covers patients with paroxysmal AF) with adequate control of rate	
☐ Presence of AF after treatment with amiodarone for at least 48 hours and one or more attempts at electrical cardioversion, with adequate control of rate	

Hospital Discharge

5. Was patient discharged by 60 (+/- 5) days following randomization O No O Yes

Date of Index Hospital Discharge: ☐☐/☐☐☐/☐☐☐☐ (d d m m m y y y y)

Time of Index Hospital Discharge ☐☐:☐☐ (24 hour clock)

Patient ID: ☐☐-☐☐☐

Status	Assessment Date	If Not done, specify reason
☐ Not done	☐☐/☐☐☐/☐☐☐☐ (d d m m m y y y y)	
Overall Rhythm Assessment	O No AF O AF O Unable to confirm Rhythm - _____	

Patient ID: ☐☐-☐☐☐

Visit Status	O Not Done O Done
If done, date of visit	☐☐/☐☐☐/☐☐☐☐ d d m m m y y y y

Patient ID: ☐☐-☐☐☐

Readmission ID: ☐☐

O Emergency Department O Hospitalization O Short stay <24 hours

1. Date of Admission: ☐☐/☐☐☐/☐☐☐☐ (d d m m m y y y y)

2. Time of Admission ☐☐:☐☐ (24 hour clock)

3. Reason for Visit/Stay

O Cardiovascular

O Atrial Fibrillation management/treatment

O Other cardiovascular

O Non cardiovascular

Is ED visit /Rehospitalization/Short stay due to an Adverse Event? O No O Yes

if yes, enter Adverse Event I.D. ☐☐

Discharge

4. Date of Discharge: ☐☐/☐☐☐/☐☐☐☐ (d d m m m y y y y)

5. Time of Discharge ☐☐:☐☐ (24 hour clock)

POAF12: ADDITIONAL PROCEDURE **1:1**

Patient ID: ☐☐-☐☐☐ **Procedure Date:** ☐☐/☐☐☐/☐☐☐☐
d d m m m y y y y

Procedure ID: ☐☐

1. Is at least one procedure related to an AE? O No O Yes If yes, Adverse Event I.D. ☐☐

2. Specify procedures performed: (check all that apply)

- ☐ Cardioversion Was normal rhythm achieved O No O Yes
- ☐ Pericardiocentesis
- ☐ Permanent pacemaker
- ☐ Sternal closing
- ☐ Thoracentesis
- ☐ Other procedure

Patient ID: ☐☐-☐☐☐ Adverse Event ID.:☐☐

1. Date of onset:	**2.Date of Resolution:**
☐☐/☐☐☐/☐☐☐☐ d d m m m y y y y	☐☐/☐☐☐/☐☐☐☐ d d m m m y y y y

3. Type of adverse event you are reporting (check one event per form submission):
O Bleeding (specify type) O Type 1 O Type 2 O Type 3: O Type 3a bleeding O Type 3b bleeding O Type 3c bleeding O Type 4: Coronary Artery Bypass Graft–related bleeding O Type 5: Fatal bleeding
O Cardiac Arrhythmias *(specify):* O Sustained ventricular arrhythmia requiring defibrillation, cardioversion or ablation O Sustained supraventricular arrhythmia other than AF or AFL requiring drug treatment, cardioversion or ablation O Cardiac conduction abnormalities requiring permanent pacemaker O QTc prolongation > 500ms
O Cerebrovascular thromboembolism *(specify):* O Stroke- Ischemic or Hemorrhagic O TIA
O Heart Failure
O Major Infection *(specify):*
O Endocarditis O Mediastinitis/Deep Sternal Wound Infection O Infectious Pericarditis O Sepsis O Localized Infection
O Myocardial Infarction (MI)
O Myocardial Infarction Peri- CABG
O Sudden unexpected cardiac death
O Non-cerebral Thromboembolism
O Pericardial Fluid Collection
O Pleural Effusion

O Renal Events *(specify):*
- O Risk of Renal Dysfunction
- O Injury to the Kidney
- O Failure of Kidney Function

O Thyroid Dysfunction (specify):
- O Hypothyroidism
- O Hyperthyroidism

O Other: *(specify):*

4. Seriousness of Adverse Event:

O Serious (Fatal; Life threatening; Results in significant or persistent disability; Requires hospitalization or Prolongs a hospital stay, results in a congenital anomaly/birth defect)

O Not Serious

Patient ID: ☐☐-☐☐☐

Date of Death: ☐☐/☐☐☐/☐☐☐☐
d d m m m y y y y

Patient ID: ☐☐-☐☐☐

1. Date of Study completion/Early termination ☐☐/☐☐☐/☐☐☐☐
   d d m m m y y y y

2. Did the subject complete the study? O No O Yes

If no, specify primary reason for early study exit:

O Death. Complete mortality form.
O Investigator decision to withdraw patient
O Patient withdrawal of consent
O Lost to follow-up.
O Other

Patient ID: ☐☐-☐☐☐

Row ID	Medication Name *Dropdown menu of Cardiovascular Medications*	Start Date DD-MMM-YYYY	Dose	Unit *Dropdown menu:* mg mL ug; mcg uL mcg/kg/min meq Kg/min Mcg/min IU	Route *Dropdown menu:* [IM] INTRAMUSCULAR AURICULAR (OTIC) [IV] INTRAVENOUS [IV BOLUS] INTRAVENOUS BOLUS [IV DRIP] INTRAVENOUS DRIP NASAL [NG]NASOGASTRIC ORAL [SC] SUBCUTANEOUS [SL] SUBLINGUAL [OTIC] AURICULAR BUCCAL CONJUNCTIVAL CUTANEOUS [E-TRACHE] ENDOTRACHEAL HEMODIALYSIS [I-DERMAL] INTRADERMAL [I-GASTRIC] INTRAGASTRIC [I-OCUL] INTRAOCULAR OPHTHALMIC OROPHARYNGEAL PARENTERAL PERCUTANEOUS RECTAL RESPIRATORY (INHALATION) [S-MUCOS] SUBMUCOSAL TOPICAL [T-DERMAL] TRANSDERMAL [T-MUCOS] TRANSMUCOSAL	Frequency *Dropdown menu:* BID PRN QH Q2H Q3H Q4H QD QID QOD TID; TDS ONE TIME DOSE TITRATION THERAPEUTIC DOSE	Stop Date DD-MMM-YYYY	Ongoing at Study Completion
1.	**[AMIODARONE] CORDARONE; PACERONE**							
2.								
3.								

Patient ID: ☐☐-☐☐☐

Adverse Event ID# ☐☐

ADVERSE EVENT ADJUDICATION

To be completed by the EAC committee only	
Date of Adjudication	☐☐/☐☐☐/☐☐☐☐ d d m m m y y y y
Overall Event Assessment	O Agree with Adverse Event Classification O Disagree with Adverse Event Classification

ONSET DATE:	
O **Agree with Onset Date**	
O **Disagree with Onset Date** If disagree, specify Onset Date:	☐☐/☐☐☐/☐☐☐☐ d d m m m y y y y

Seriousness of Adverse Event
O Agree with Seriousness of Adverse Event Classification
O Disagree with Seriousness of Adverse Event Classification If Disagree, Reclassify: O Serious O Not Serious

AE Reclassification (please choose one, then complete appropriate section below):	
1.	O Bleeding (specify type):
	O Type 1 (Not actionable and does include treatment)
	O Type 2 (Any clinically overt sign of hemorrhage)
	O Type 3 (Clinical, laboratory, and/or imaging evidence)
	O Type 3a (Transfusion/ Hemoglobin drop)
	O Type 3b (Hemoglobin drop/ tamponade/ surgical intervention/ IV vasoactive drug)
	O Type 3c (Intracranial hemorrhage/ Intraocular bleed)
	O Type 4 (CABG-related)
	O Type 5 (Fatal)
2.	O Cardiac Arrhythmias (specify):
	O Sustained ventricular arrhythmia requiring defibrillation, cardioversion or ablation
	O Sustained supraventricular arrhythmia other than AF or AFL requiring drug treatment, cardioversion or ablation
	O Cardiac conduction abnormalities requiring permanent pacemaker
	O QTc prolongation > 500ms
3.	O Cerebrovascular thromboembolism (specify):
	O Stroke- Ischemic or Hemorrhagic
	O TIA
4.	O Heart Failure
5.	O Major Infection (specify):
	O Endocarditis
	O Mediastinitis/Deep Sternal Wound Infection
	O Infectious Pericarditis
	O Sepsis
	O Localized Infection

6.	O Myocardial Infarction
7.	O Myocardial Infarction Peri- CABG
8.	O Sudden unexpected cardiac death
9.	O Non-cerebral Thromboembolism
10.	O Pericardial Fluid Collection
11.	O Pleural Effusion
12.	O Renal Events (specify):
	O Risk of Renal Dysfunction
	O Injury to the Kidney
	O Failure of Kidney Function
13.	O Thyroid Dysfunction(specify):
	O Hypothyroidism
	O Hyperthyroidism
14.	O Other Serious Adverse Event, specify: _____