WISDOM

Working to Improve discuSsions about DefibrillatOr Management

1R01HL102084

Manual of Procedures v4.1

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Purpose of the Manual of Procedures

Welcome to the Working to Improve discuSsions about Implantable DefibrillatOr Management (WISDOM) trial. You are very important to the success of this study. This manual will guide you in your duties and outline the procedures to be followed for this study. Section I of this manual will provide a general overview of the study and the roles that each member of the research team plays. Section II will provide detailed instructions about the enrollment process, and Section III discusses the data collection procedures. Section IV describes the intervention procedures. Section V contains the forms and data collection instruments. Section VI describes definitions of adverse events and the procedures to be followed if they occur. The remainder of the manual includes information about site visits (Section VII), contact information for all study personnel (section VIII), an appendix of supplementary materials (Section IX) and references (Section X). Thank you for your work and dedication to our study!

Abstract

An Implantable Cardioverter-Defibrillator (ICD) is a device implanted in a patient's chest to monitor the heart rhythm and deliver shocks to terminate potentially lethal arrhythmias when necessary. While ICDs reduce sudden cardiac death, patients with these devices do eventually die, either of heart failure or other chronic diseases. As a patient's disease worsens, physiologic changes (intrinsic and extrinsic to the heart) may affect the cardiac conduction system, leading to more arrhythmias and increasing the frequency of shocks. Because ICD shocks can cause pain and anxiety and may not prolong a life of acceptable quality, it is appropriate to consider ICD deactivation as a patient's clinical status worsens and death is near. However, these conversations rarely occur. We propose to conduct a randomized clinical trial of a physician-centered patient counseling and support intervention to improve communication between clinicians and patients with ICDs. The goals of the study are to determine the effectiveness of the intervention to: 1) increase conversations about ICD deactivation, 2) increase the number of patients who have their devices deactivated, and 3) improve mental health outcomes for bereaved caregivers of deceased patients. The unit of randomization is the hospital, the intervention is aimed at heart failure clinicians, and the unit of analysis is the patient. We have created a network of six academic medical centers across the country. The intervention to be delivered consists of three parts. First, the PI will conduct a workshop on communication specific to ICD-deactivation with heart failure clinicians at the intervention centers. Second, when enrolled patients are admitted to the hospital or seen in the outpatient setting, the heart failure clinician will receive two reminders (one via email, one in the patient chart) that the patient is appropriate for a conversation about ICD deactivation. Finally, clinicians will receive aggregated feedback about the number of conversations they have conducted and data on patients' satisfaction with conversations every six months. Physicians at usual care hospitals receive a didactic lecture on advance care planning. All patients and surrogates will be interviewed at baseline and

then assessed at regular intervals to determine the outcomes of: 1) the prevalence of conversations about ICD deactivation as reported by the patient/surrogate; and 2) the frequency with which patients have their devices deactivated. Caregivers will continue to be interviewed at regular intervals up to 6 months after the patient dies to determine the relationship of the intervention to caregiver mental health outcomes. Given the exponential increase in the number of patients with ICDs, this intervention has the potential to improve the quality of care for thousands of patients near the end of life and their families.

Version Control

Version	Date	Author	Changes	Reason
1.1	5/15/11	Goldstein	Initial creation of protocol	
1.2	6/6/11	Goldstein	First revision of protocol	
1.3	6/13/11	Goldstein	Second revision before training meeting	
1.4	6/24/11	Goldstein, Herasme	First revision following training meeting	
	9/12/2011	Herasme	Updated Instruments	
	10/11/2011	Herasme	Updated Instruments	
	10/26/2011	Herasme	Updated Instruments	
	11/10/2011	Herasme	Updated Instruments	
	1/23/2012	Herasme	Updated Study Eligibility Criteria and Instruments	
	2/9/2012	Herasme	Updated Instruments	
	2/15/2012	Herasme	Updated Flows	
	2/16/2012	Herasme	Updated Flows	
2.0	8/30/2012	Herasme	Updated Study Eligibility Criteria and Instruments	New criteria to include VAD and transplant candidates
3.0	4/24/2013	Herasme	Clarified Chart Abstractions Requirements	
3.1	5/15/2013	Herasme	Clarified instructions for caregiver follow-up if patient withdraws	
4.0	1/20/2014	Helmus	Self-administered surveys updated; Inpatient/Outpatient eligibility criteria and instruments updated; Clarified screen failure	

			classifications; Incorporates questions/answers from RC calls	
4.1	4/9/2014	Helmus	Operationalizes IV treatment eligibility criteria	

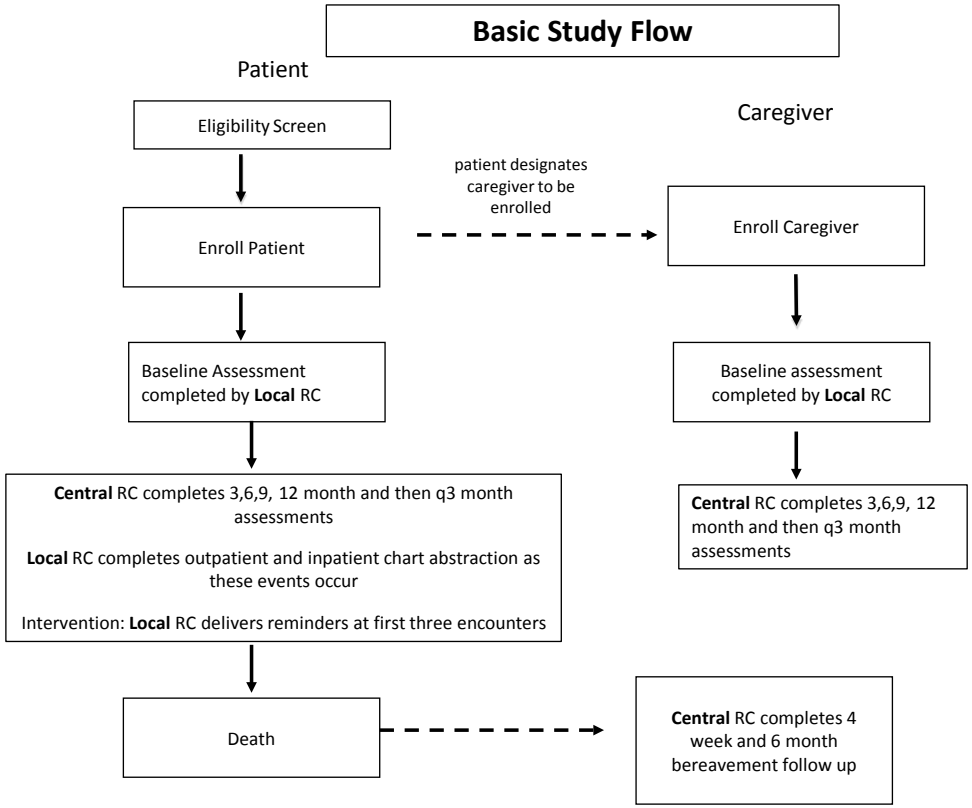
Abbreviations

CATI	Computer Assisted Telephone Interview
DSM	Diagnostic and Statistical Manual of Mental Disorders
EDC	Electronic Data Capture
EF	Ejection Fraction
EMR	Electronic Medical Record
HIPAA	Health Insurance Portability and Accountability Act
ICD	Implantable Cardioverter Defibrillator
MOP	Manual of Procedures
MRA	Medical Record Abstraction
PHI	Protected Health Information
PI	Principal Investigator
PM	Project Manager
RC	Research Coordinator
SASE	Self-Addressed Stamped Envelope
SCID	Structured Clinical Interview for the DSM
SHFM	Seattle Heart Failure Model
WISDOM	Working to Improve discuSsions about DefibrillatOr Management

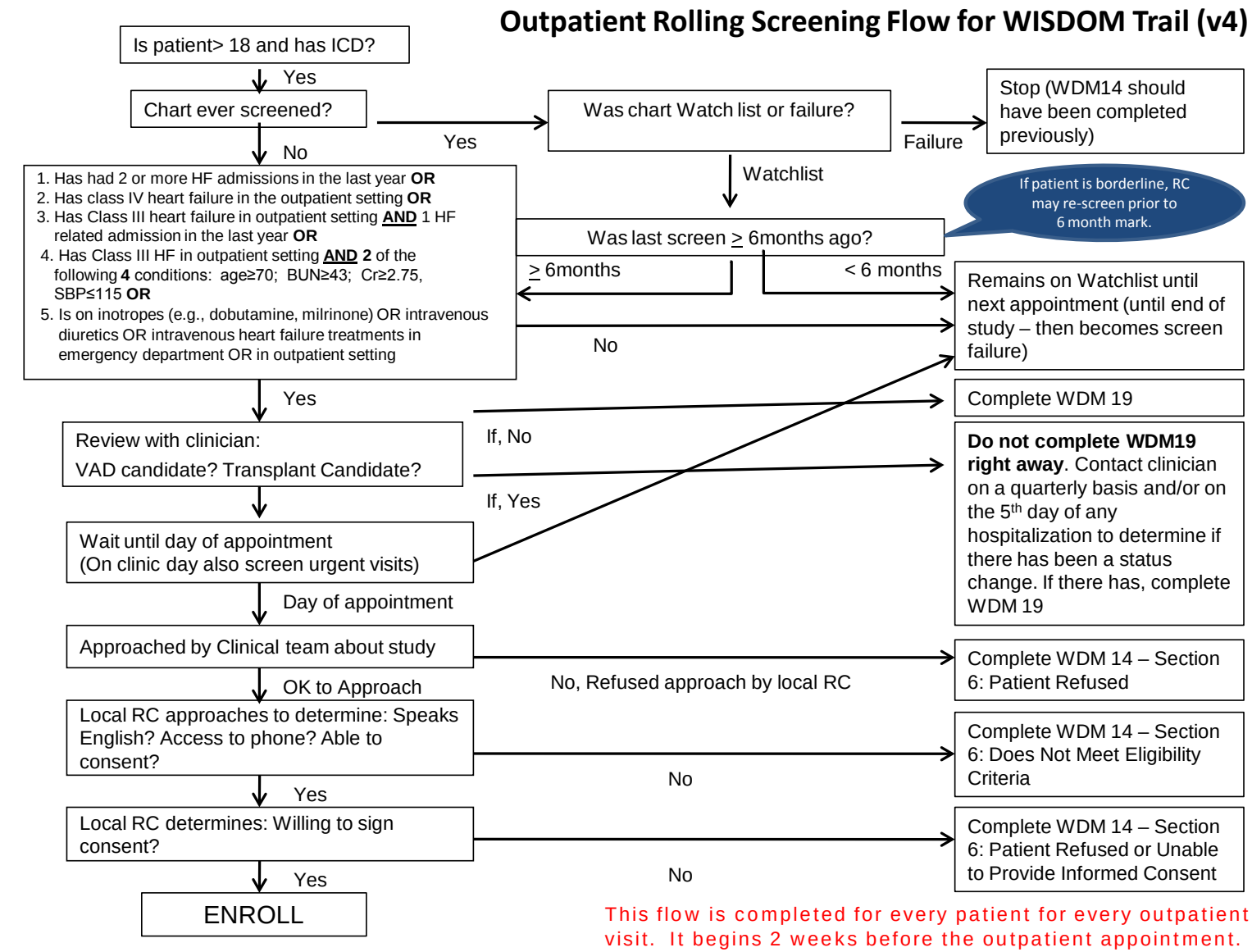
I. Overview

Study Flow

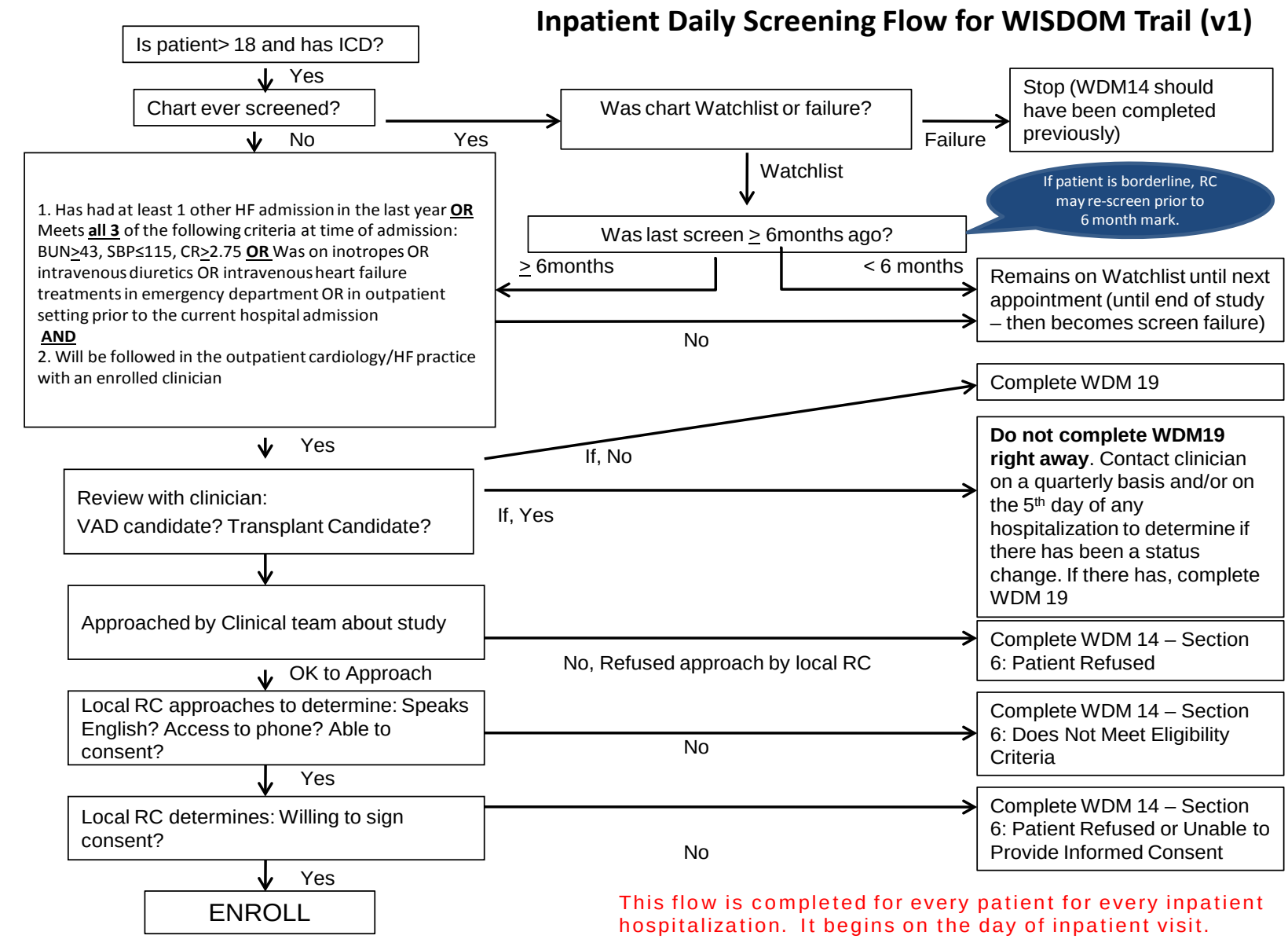
Basic Study Flow



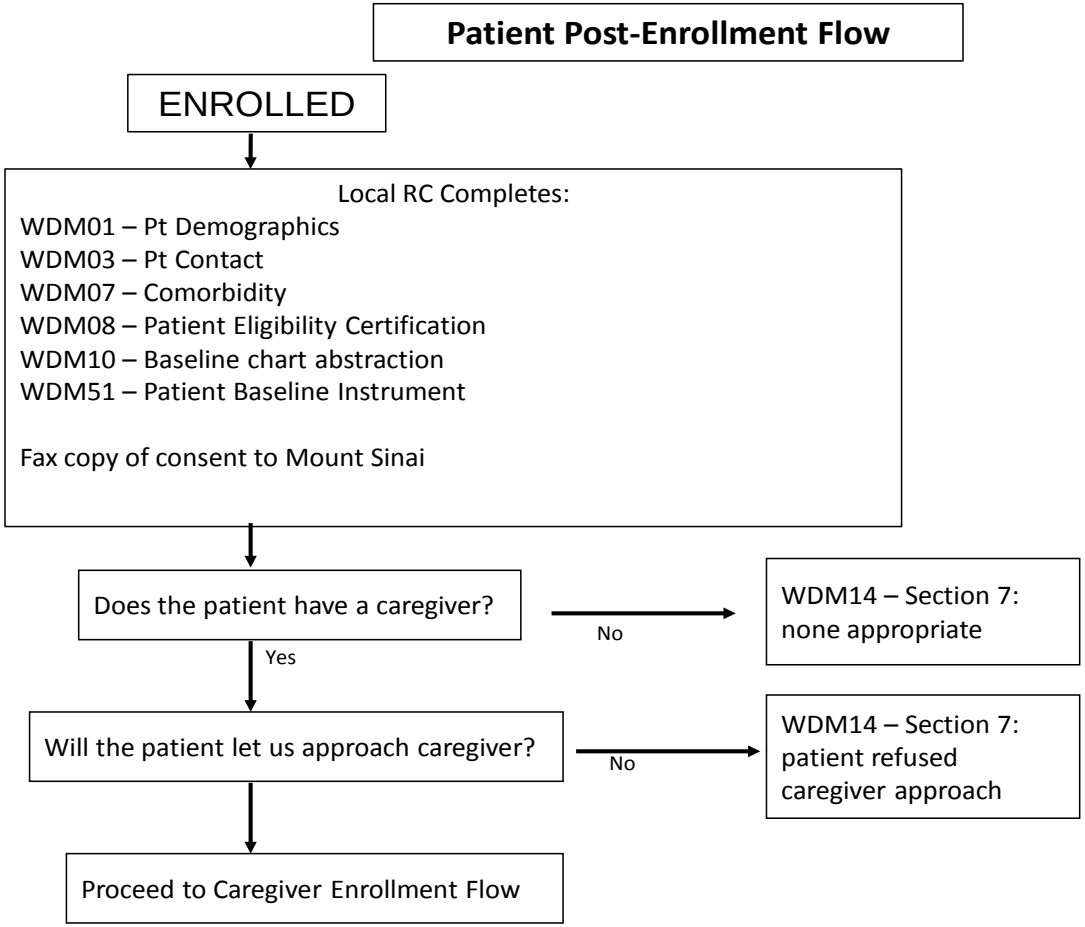
Outpatient Rolling Screening Flow



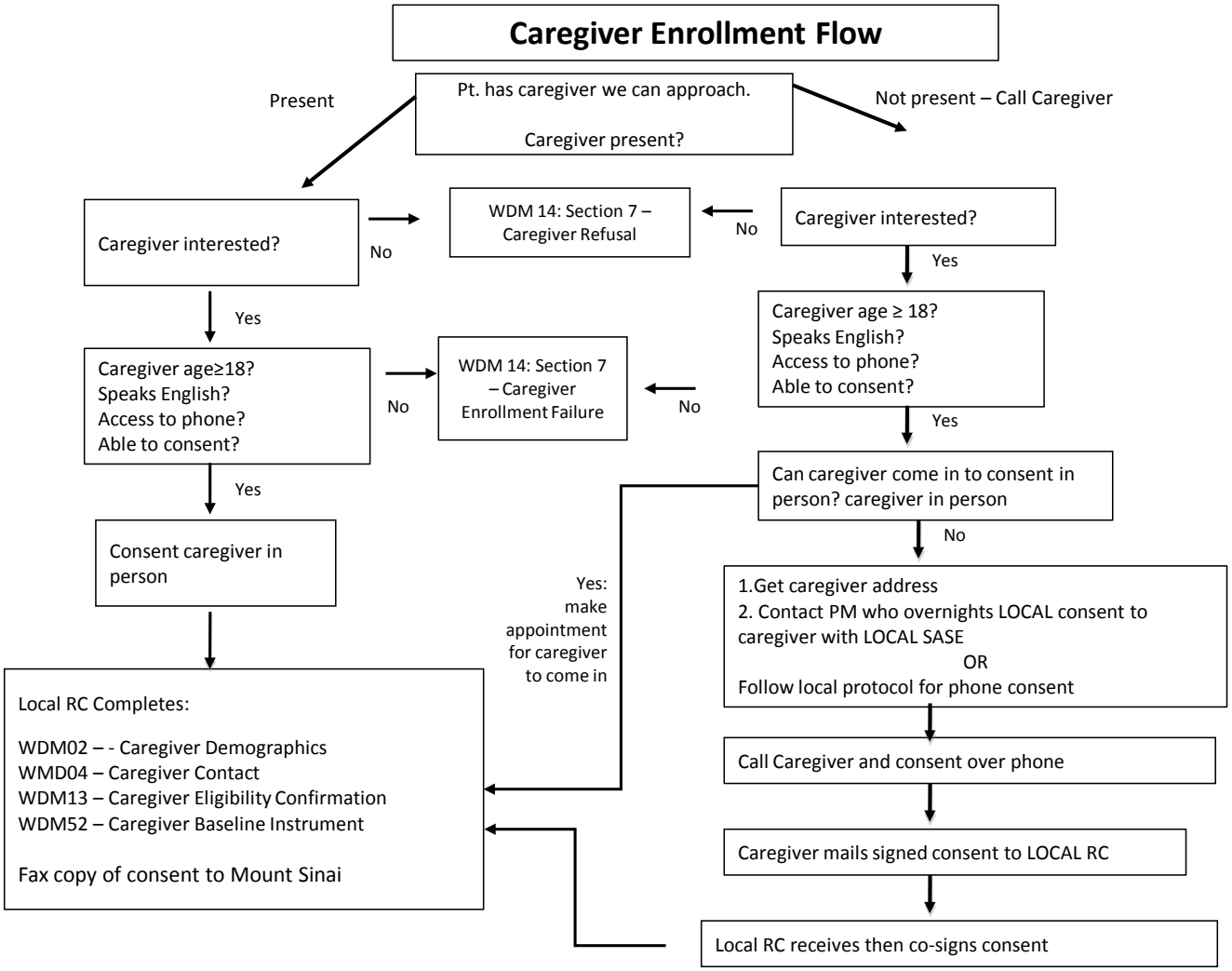
Inpatient Daily Screening Flow



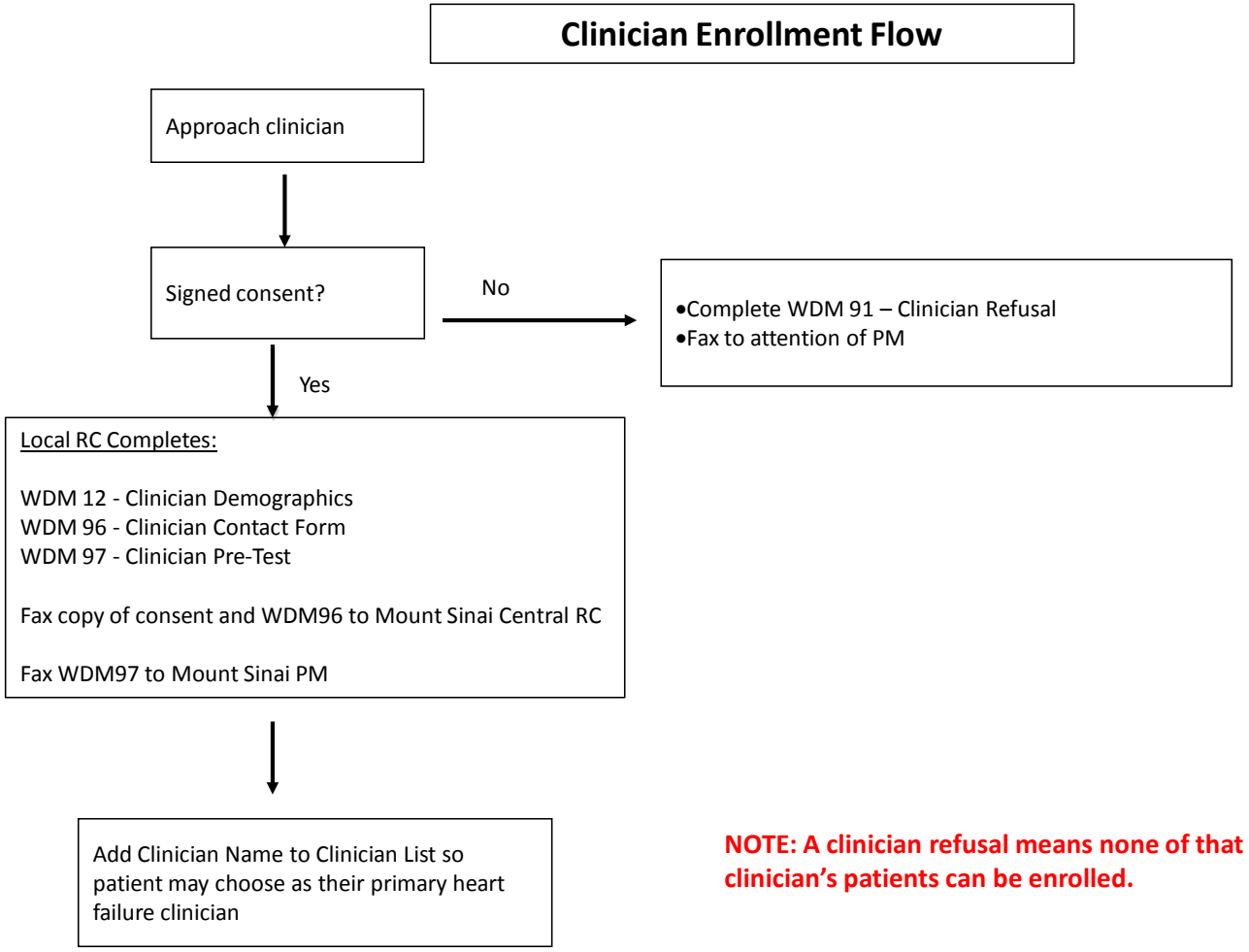
Patient Post-Enrollment Flow (picks up from patient enrollment on last flow)



Enrollment Flow - Caregiver

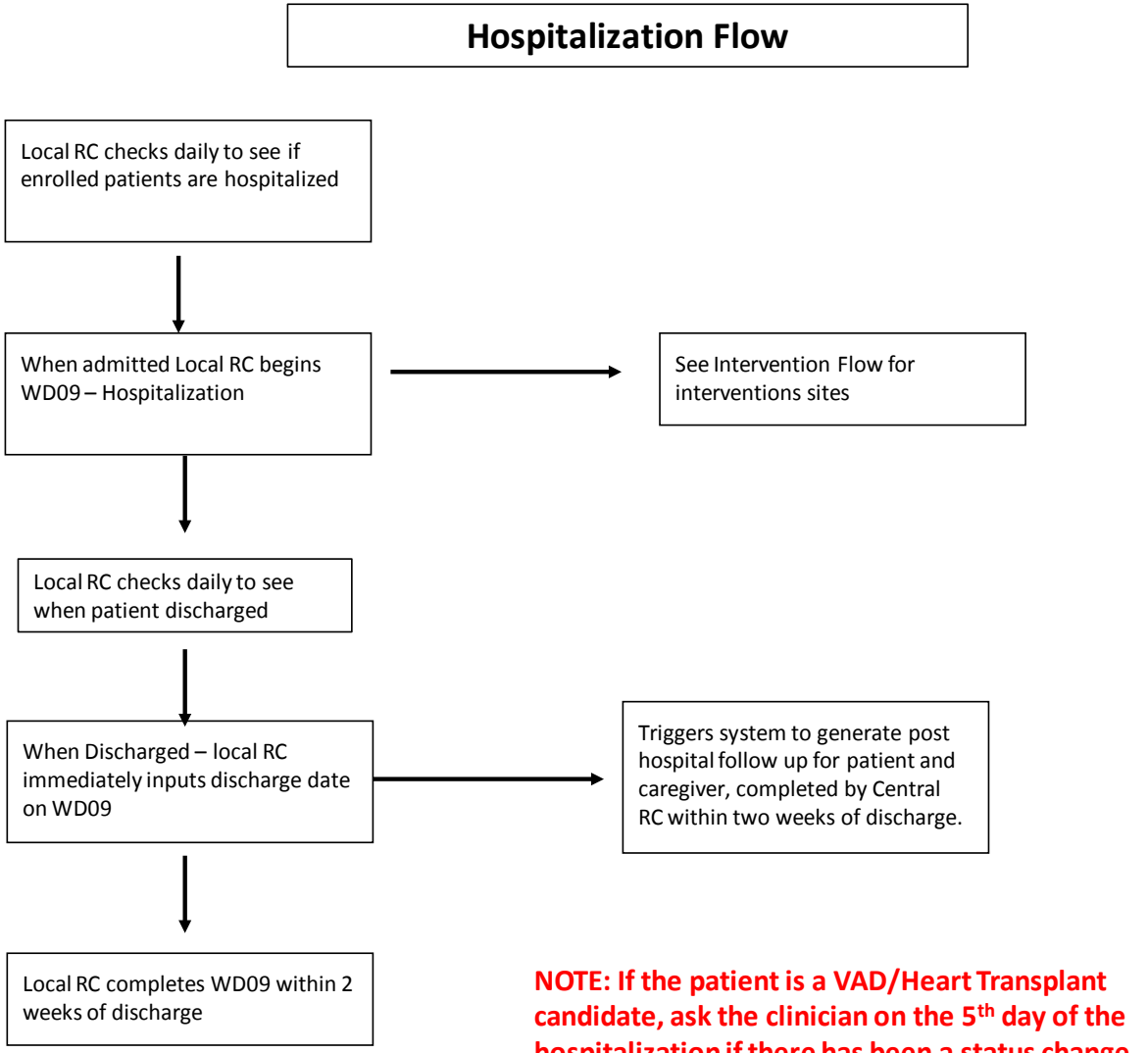


Enrollment Flow - Clinician



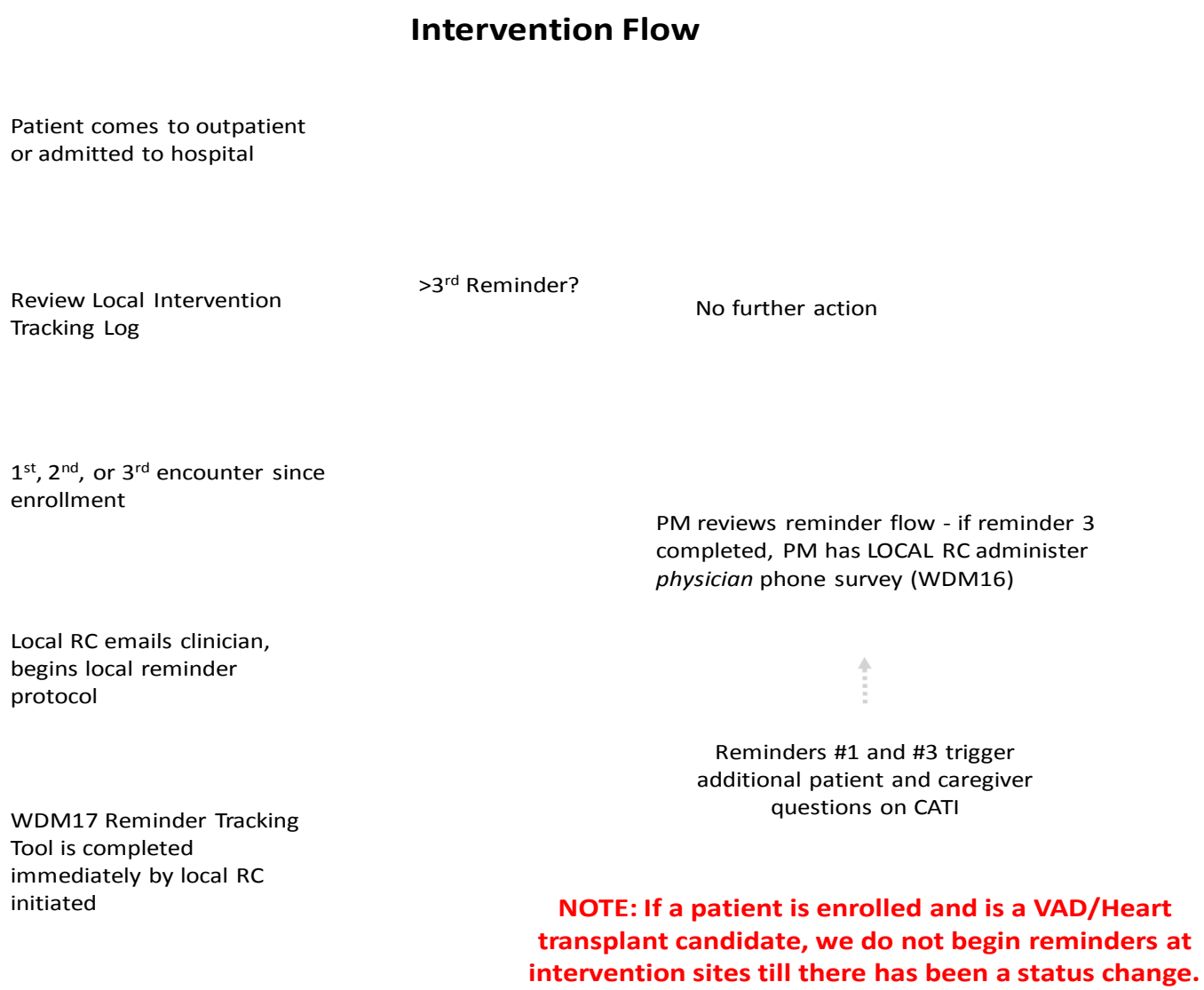
NOTE: A clinician refusal means none of that clinician's patients can be enrolled.

Patient Hospitalization Flow

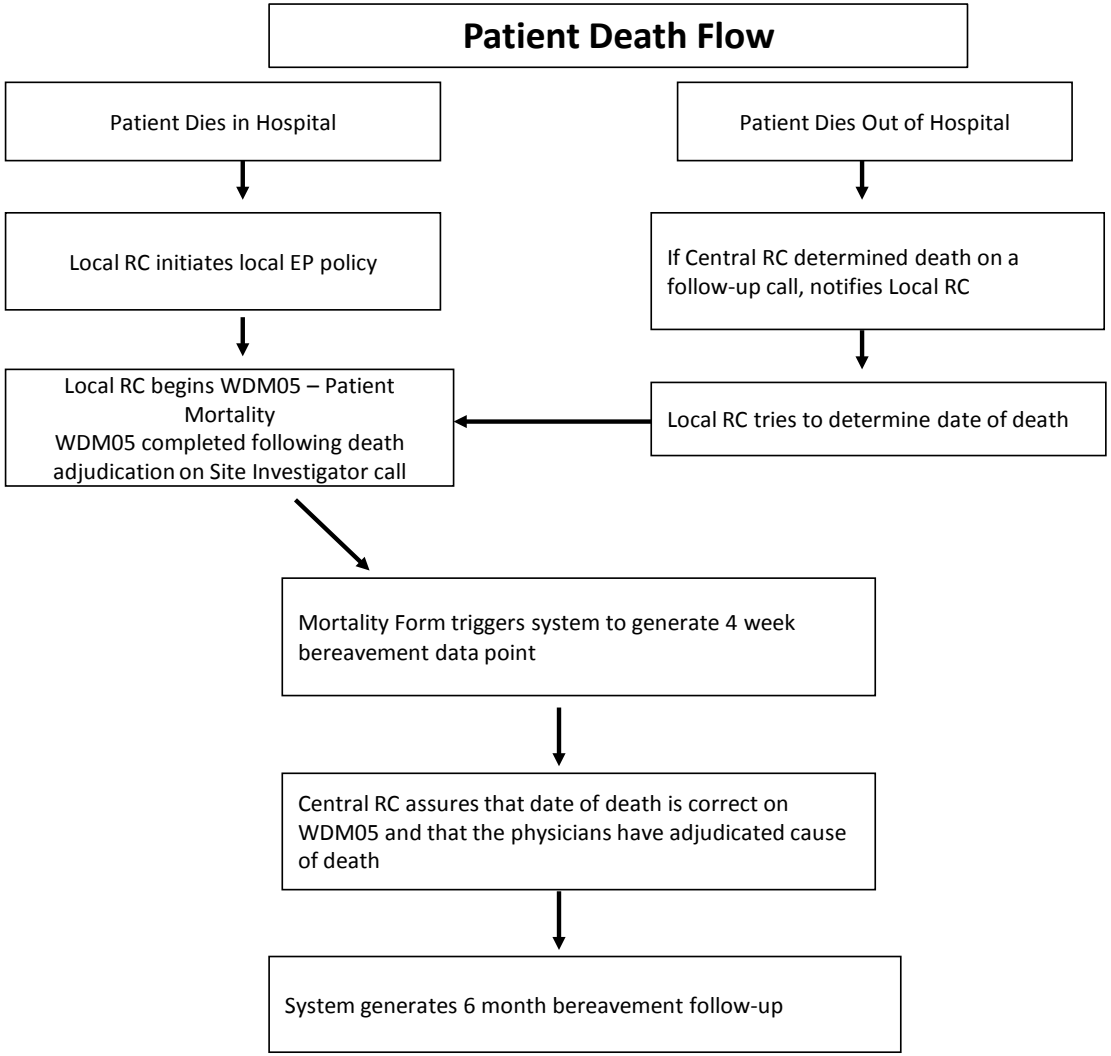


NOTE: If the patient is a VAD/Heart Transplant candidate, ask the clinician on the 5th day of the hospitalization if there has been a status change .

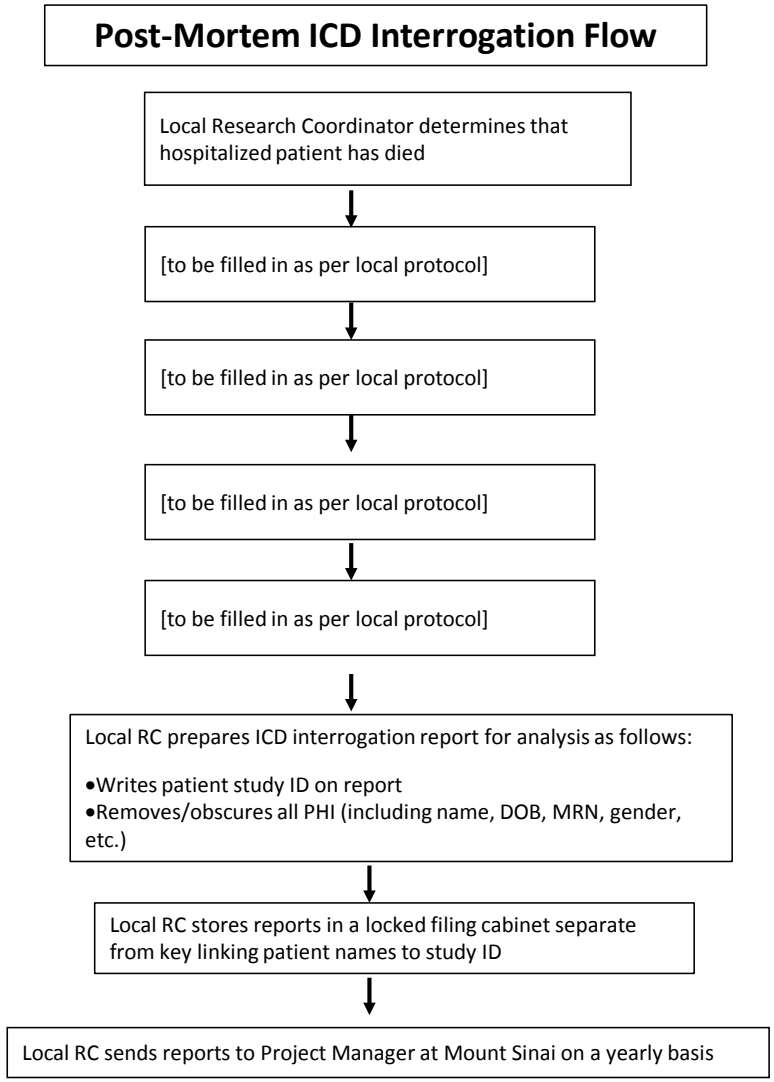
Intervention Flow



Patient Death Flow



Post-Mortem ICD Interrogation Flow



Roles and Responsibilities

Principal Investigator

- Oversee all aspects of grant
- Oversight of enrollment, conduct of study protocol, and adherence
- Oversight of data collection and analyses, data sharing, and transmission
- Communicate with NHLBI, complete reports
- Adjudicate adverse events
- Assure human subjects regulations followed at all sites
- Collaborate and have regular meetings with site PIs and research staff
- Perform site visits to assure all procedures related to study flow and data collection are followed

Co-Investigators

- Assist PI with their particular areas of expertise
- Work with PI adjudicating adverse events
- Review enrollment and missing data reports with PI to identify trends and areas for improvement
- Assist with adjudication of adverse events as needed

Site Investigators

- Responsible for overall conduct of study at site
- Oversee local RC and assure compliance with human subjects and HIPAA specifications
- Monitor staff productivity, performance, rate of enrollment, accurate and complete adherence to study protocols
- Assist local RC with enrolling heart failure clinicians
- At intervention sites – assist RC with delivery of aggregated feedback reports to local clinicians
- Assure compliance with successful training of all research staff
- At intervention sites – assure new clinicians undergo communication training

Project Manager

- Oversee all aspects of data collection and subject recruitment
- Work as liaison between local sites, PI, Co-Investigators
    - Lead weekly calls between RCs
    - Coordinate monthly calls between Site Investigators
- Work as liaison between local sites and central data collection team
- Assess data collection to assure data quality and completeness
- Create monthly enrollment reports, missing data reports, quarterly adverse event reports
- Oversight and coordination of recruitment and training of study staff
- Oversight and coordination of enrollment procedures, conduct of and adherence to protocol, data management, assure regular communication structures for all research staff

- Intervention only:
    - Create aggregate feedback reports to be delivered to clinicians
    - Monitor timeliness of Reminder Tracking Tool
- Accompany PI on site visits as needed

Local RCs

- Perform chart reviews to determine eligibility, and review eligibility criteria with heart failure clinicians
- Enroll local clinicians
- Enroll patients and caregivers, complete consent documents, and enter contact information into EDC
- Perform baseline assessment of patients and caregivers
- Perform daily checks of hospital system to determine when patients are admitted or have outpatient heart failure appointment
- Complete hospital and outpatient medical record abstraction forms
- Complete patient mortality forms when RC learns of patient death
- Participate in weekly calls with other local RCs and project manager
- Intervention only:
    - Deliver reminders
    - Complete reminder tracking tool within 24 hours of reminder being delivered
    - Complete physician phone interview if conversation doesn't occur

Central RC

- Complete all follow-up assessments for patients and caregivers (including bereavement assessments) using the CATI system
- Assure mortality reports (WDM05) have accurate dates and causes of death (after discussing with site PI)
- Maintains copy of consent forms for all locations in secure location

Data Management Team

- Build EDC and CATI
- Train and provide technical support to research staff
- Assist with database management / troubleshooting

Advisory Panel

- Assist with project development according to areas of expertise
- Review Adverse Events on a twice yearly basis

II. Enrollment

This enrollment guide outlines the procedures for assessing patient eligibility and enrolling patients; assessing caregiver eligibility and enrolling caregivers; and enrolling clinicians. When reading this section, keep in mind that there are three sets of subjects: patients, caregivers, and clinicians.

Use of Deception in the Enrollment Process

The nature of this study makes it necessary to employ deception in the enrollment of patients and caregivers for the following reasons:

1. The objective of this study is to create a conversation about ICD deactivation, and as part of this conversation to inform patients of their prognosis and that they have a limited life expectancy. As such, we cannot inform patients about their risk of dying in the consent procedures because many patients/caregivers will have not heard this information before, and the time of study consent is not an appropriate venue for such conversations.
2. By explaining the true nature of the study, it puts the research coordinator in the position of having to tell patients about their prognosis, an inappropriate role for the RC. The goal of the study is to increase these conversations between clinicians and patients.
3. Letting the patients/caregivers know that this is a study about deactivation will create a “Hawthorne Effect” (where asking about a study becomes an intervention in itself). Our previous data have shown that patients and their caregivers rarely know that deactivating an ICD at the end of the patient’s life is an option.[1-2] The goal of the study is to determine if we can increase the rate of discussions between clinicians and patients/families. Telling them that the study is about deactivation would actually encourage them to discuss this with their caregiver and create an artificial method for communication. Thus the consent form would become an intervention, and would not only alter the results of the study itself but also not be reproducible. In addition to changing the title of the study for patients and caregivers, we will indicate that the purpose of the study is “to explore symptoms and quality of life in patients with ICDs and their caregivers.” Likewise informing them that their prognosis is poor would also create opportunities for conversations that are not naturally occurring and would affect the results of the study.
4. Not all patients/caregivers will be at intervention sites, and the intervention is focused on the clinicians, not the patient/caregiver. Thus we have removed the word intervention from the title that is used on patient and caregiver consents.
5. The survey instruments ask about physical and emotional symptoms as well as quality of life. As such, referring to the study and describing it as being about symptoms and quality of life is not truly deception, as

these are core elements of the data collection and are actual outcomes of the study for the caregiver.

Note that the deception used in the study will not be revealed to patients and their caregivers. Even at the end of the study, patients may be alive and thus the same issues about not informing them at consent apply at study termination. It is unclear what benefit revealing the study design to bereaved caregivers would be at the end of the study, although there might be clear burdens. Thus the burden of revealing the deception at the end of the study for caregivers of deceased patients far outweighs the benefit.

Projected Enrollment

The chart below demonstrates the projected enrollment for patients across all sites. The assumption is that each site will recruit between 2-3 patients/month (43 patients per quarter ÷ 3 months / quarter ÷ 6 sites = 2.3 patients / month / site).

Calendar Year	1st Quarter Jan - Mar	2nd Quarter Apr - June	3rd Quarter July - Sep	4th Quarter Oct - Dec	Total
2011			6	18	24
2012	36	43	43	43	165
2013	43	43	43	43	172
2014	43	43	43	43	172
2015	43	16	0 (follow-up)	0 (follow-up)	59
2016	(ends 1/31/ 2016)				0
Total	165	145	135	147	592

These data are reported to NHLBI every quarter.

The goal of the study is to enroll one caregiver for every patient. However, we will enroll patients who do not have a caregiver. (This is a change from the original grant application.)

Eligibility Criteria

What are the eligibility criteria?
The eligibility criteria for patients are as follows:

FOR ALL PATIENTS:

- Patient is ≥ 18 years old*
- Patient has an ICD*
- Patient does not currently have a VAD
- Patient speaks English
- Patient has consistent and reliable access to a phone

FOR OUTPATIENTS (i.e. for patients *screened* in the outpatient setting)**:**

- Has had 2 or more heart failure related admissions in the last year
  OR
- Has class IV heart failure in the outpatient setting
  OR
- Has Class III heart failure in outpatient setting AND 1 heart failure related admission in the last year
  OR
- Has Class III heart failure in outpatient setting AND 2 of the following 4 conditions: age≥70; BUN≥43; Cr≥2.75, SBP≤115
  OR
- Is on inotropes (e.g., dobutamine, milrinone) OR intravenous diuretics OR intravenous heart failure treatments in emergency department OR in outpatient setting**
  - For patients to be eligible with this criteria, patients need 2 ER/outpatient IV Lasix treatments in the last 6 months **OR** an ER/outpatient IV Lasix treatment in combination with other outpatient eligibility criteria, interchanging "hospitalization" with ER/outpatient IV Lasix treatment **OR** on home inotropes.
  - An ER/outpatient IV treatment should only be counted if within the last 6 months.

  Examples:
  A patient would be eligible if:
    - The patient has 2 ER/outpatient IV Lasix treatments in the last 6 months.
    - The patient has 1 hospital admission in the last 12 months and 1 ER/outpatient IV Lasix in the last 6 months.
    - The patient has Class III Heart Failure and 1 ER/outpatient IV Lasix in the last 6 months.
    - The patient is on home inotropes.

FOR INPATIENTS (i.e. for patients *screened* in the inpatient setting)**:**

- Has had at least 1 other HF admission in the last year
  OR
- Meets all three of the following criteria/parameters at time of admission: BUN≥43, SBP≤115, CR≥2.75
  OR
- Was on inotropes OR intravenous diuretics OR intravenous heart failure treatments in emergency department OR in outpatient setting prior to the current hospital admission**
  - For patients to be eligible with this criteria, patients need 1 ER/outpatient IV Lasix treatment in the last 6 months **OR** on home inotropes.
  - An ER/outpatient IV treatment should only be counted if within the last 6 months.

  Examples:
  A patient would be eligible if:
  - The patient is currently admitted to the hospital and has 1 ER/outpatient IV Lasix in last 6 months.
  - The patient was on home inotropes prior to the current hospital admission.

  AND
- Will be followed in the outpatient cardiology/HF practice with an enrolled clinician

*Charts of patients that are younger than 18 years of age and/or who do not have an ICD are not screened. No forms are completed for these patients.

****Note:** It may be easier to think of the word "hospitalization" as meaning one admission to the hospital OR a visit to ER in last 6 months where got IV Lasix **OR** an outpatient clinic appointment in last 6 months where got IV Lasix. Hospital admissions should be counted if within the last 12 months, whereas ER/outpatient IV treatments should be counted if within the last 6 months.

For the purposes of screening, patients classified as a NYHA II-III heart failure are screened as a NYHA class II heart failure. Similarly, patients classified as a NYHA III-IV heart failure are screened as NYHA class III heart failure.

As of August 1, 2012, being a candidate for a VAD or heart transplant is no longer an exclusion criteria. That is, we are now enrolling patients who are candidates for VADs or cardiac transplants

Heart failure-related admission

Heart Failure related includes admissions for worsening cardiac function as well as shortness of breath, worsening edema, or worsening renal failure. Admissions related to ICD shocks should be counted towards heart failure admissions. Admissions for generator changes or lead replacement should not be counted, unless there are clear heart failure complications that occur during the course of the admission. Cause of admission is not the same as the final DRG coding, and billing codes should not be used for eligibility purposes. To determine the cause of the admission, the chart will need to be reviewed (although often the admission notes are sufficient.) The last 12 months is considered for any time the patient spent in the hospital in the last 12 months. That is, if the admission date was 12.5 months ago, but the patient was still in the hospital 12 months ago – this is a HF related admission even though the admit date was slightly in excess of 12 months.

When is eligibility screening done?

Eligibility screening occurs on a "rolling" basis.

Outpatient

The outpatient schedule is reviewed regularly (daily or weekly) to determine which patients are coming in two weeks from the current date. These charts are then screened as per the outpatient enrollment flow screening diagram. If the patient is just shy of meeting the eligibility criteria (i.e. Patient has only had 1 HF admission in the last year or is a NYHA class III with no HF admissions, or is a NYHA class III and only meets one of the listed parameters) that patient may be placed on Watchlist and may be re-screened at their subsequent visit to determine any change in eligibility. Otherwise, the patient is placed on Watchlist and re-screened every six months. Any screening done before the 6 month mark should be treated as 'one screening'. See Eligibility Screening Tool for more details.

For patients who present as "walk-ins" (i.e. those who were not scheduled two weeks before their appointments) their chart is screened the day they come in and then placed in either the "Watchlist" folder or "Eligible" folder to be approached at their next appointment.

Inpatient

The inpatient schedule is reviewed regularly (daily or every other day) to determine if there are any admitted patients that may be eligible for the study. The charts are screened as per the inpatient enrollment screening flow diagram. If the patient is just shy of meeting the eligibility criteria (i.e. Patient has only had 1 HF admission in the last year [not including present admission] or only meets 1/3 or 2/3 of the required parameters) that patient may be placed on Watchlist and may be re-screened at their subsequent visit to determine any change in eligibility. Otherwise, the patient is placed on Watchlist and re-screened every six months. Any screening done before the 6 month mark should be treated as 'one screening'. See Eligibility Screening Tool for more details.

Note: For patients enrolled in the inpatient setting do both a baseline chart abstraction and a hospitalization chart abstraction. WDM10: The baseline chart abstraction will be based on the information in EMR **for the first day of admission**. If certain lab values are not available for that day, we can use lab values that are no more than for 4 weeks old (see section on WDM10 below for more details). **WDM09:** The hospitalization chart abstraction is completed based on the information available for the duration of the hospitalization (see section on WDM09 for more details). In other words we treat it the same as we would any other hospitalization.

******If a patient is enrolled inpatient at an intervention site reminders begin on the next day of admission.******

WDM90 - Eligibility Screening Tool

A separate WDM90-eligibility screening tool is used for each patient who is screened. (Do not complete WDM90 for patients <18 years old and/or who do not have an ICD.) This is a paper form, which is maintained for the life of the study at the local site. The tool categorizes patients into three groups – Eligible, Watchlist and Not Eligible. The management of the Watchlist is covered below. However, at the end of the study– each of the WDM90 forms should have a final designation as either eligible or ineligible. Note: subjects may be screened up to 10 times before generating a screen failure ID (WDM14). For subjects that are screened before the 6 month re-screening period because they borderline in terms of meeting eligibility, any screening before the 6 month mark is counted as one screening unless they become a screen failure. For example if John Smith is screened on Jan 1st and is found to have one heart failure admission, we will continue to monitor him at every scheduled visit but every screening done before the 6 month mark will be considered as one till June 1st unless he becomes a screen before that time.

Because WDM90 contains patient identifiable information, it is stored in a locked filing cabinet at each site in a locked office. We recommend creating three folders: Eligible, Watchlist, and Non-Eligible. At the end of the study, the Watchlist folder should be empty, with all WDM90s forms having been resorted into the appropriate folder with a final categorization of either Eligible or Not Eligible.

PART ONE:

Patients who do not have an ICD are not eligible for the study, nor are patients who are younger than age 18. These questions are here only to verify eligibility – no forms are completed for patients who do not meet these criteria.

PART TWO:

The next part of the screening tool is Clinical Criteria. If part one of the screening is met, the RC then goes on to review if the subject meets the second part of the

study eligibility criteria. Study eligibility differs depending on whether the patient is screened in the outpatient or inpatient setting. The eligibility for outpatient and inpatient are listed on page 14-15.

PART THREE:
The RC (or RC and Site Investigator) contact the heart failure clinician to review the charts of patients who are eligible based on the criteria in Parts 1 and 2. The HF clinician should be asked "Based on your knowledge of this patient, do you consider him/her a candidate for a ventricular assist device or heart transplant?" If the patient is **NOT** a candidate for any of these procedures, the RC may complete WDM19. If the patient **IS** a candidate for either of these therapies, the RC does not complete WDM19 right away. See section on WDM19 for more details on when to complete this form for this scenario.

Do not specifically ask the clinician if the patient may be enrolled, but the clinician may note that the patient shouldn't be enrolled. This should count as a clinician refusal, and should be noted on WDM14.

PART FOUR:
Once the patient is determined to be eligible, the HF clinician should be asked the "surprise" question[5-6] for every patient who is eligible as follows: "Would you be surprised if this patient died in the next year?" This is not related to eligibility, but should be asked for every patient.

Note: Those patients who at the end of the study were never found to be eligible are ultimately marked as ineligible.

PART FIVE:
A Seattle Heart Failure Model score should be calculated for every patient that is 'enrolled' into the study. The SHFM creates a predictive mortality score based on clinical characteristics of the patient.[3] It can be found at **http://depts.washington.edu/shfm/**. Alternatively, a version can be downloaded to the desktop of the local RC so the values can be calculated without having to be connected to the internet.

Directions for completing the SHFM are below. In brief, the values are abstracted from the patient's chart (using the most recent data). Data are collected from inpatient or outpatient visits.

After computing the SHFM score for each patient, print the screen shot, write the date on it, and attach it to WDM90-Eligibility Screening Tool for those patients that are enrolled ONLY.

Abstraction Guide to Seattle Heart Failure Model
The individual elements of the SHFM are described below. **Use the most recent data found in the chart**. This may be difficult, because some elements

(blood pressure) are noted frequently; others (NYHA class) may be rarely noted. The window for more difficult to find items (NYHA class, uric acid) may be very long – but there is no limitation on this window for the data collected for the model. Data can come from either the inpatient or outpatient charts.

<table>
<tr><td>Age</td><td>This is age at same time as data are abstracted. Note the SHFM only allows an age range between 18 thru 85. If the patient is greater than 85, increase the mortality by 1% for every 4 years greater than 85.</td></tr>
<tr><td>NYHA Class</td><td>New York Heart Association Class of Heart Failure – a marker of the severity of a patient’s heart failure.

Can usually be found in an admission note, or as part of the history of either a cardiac cath report or echo report. Sometimes may not be specified, but can be taken from the notes. (e.g. “symptoms at rest” = class 4). Note a notation indicating the presence of Paroxysmal Nocturnal Dyspnea (PND) or Orthopnea pushes a patient up one class. (i.e. from a Class II to a Class III).

If on the most recent encounter the chart is noted as patient is between II-III, mark as III in the SHFM.

<table>
<tr><td>Class I (Mild)</td><td>No limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, or dyspnea (shortness of breath).</td></tr>
<tr><td>Class II (Mild)</td><td>Slight limitation of physical activity. Comfortable at rest, but ordinary physical activity results in fatigue, palpitation, or dyspnea.</td></tr>
<tr><td>Class III (Moderate)</td><td>Marked limitation of physical activity. Comfortable at rest, but less than ordinary activity causes fatigue, palpitation, or dyspnea.

IIIIa indicates symptoms with minimal activity, no dyspnea at rest. (Note if IIIa is noted in the chart, label as III in SHFM as IIIa is not an option)

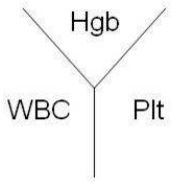
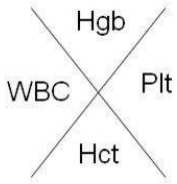
IIIb indicates symptoms with minimal activity, recent dyspnea at rest.</td></tr>
<tr><td>Class IV (Severe)</td><td>Unable to carry out any physical activity without discomfort. Symptoms of cardiac insufficiency at rest. If any physical activity is undertaken, discomfort is increased.</td></tr>
</table>
</td></tr>
<tr><td>Weight</td><td>Weight is entered in kilograms. If in pounds, weight in</td></tr>
</table>

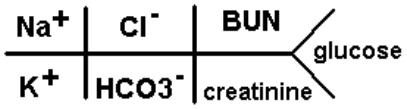
	pounds/2.2=weight in kilograms
Ejection Fraction	The % of the volume of blood in the left ventricle the heart pumps out with each contraction. This can be found in admission notes, clinic notes, or echo reports. Note that this number may vary at times. If will normally just be written "EF XX." If more than one number is found, choose the lowest (worst).
Systolic Blood Pressure	The "top" number in the blood pressure reading. (E.g. If the blood pressure is 120/80 the systolic pressure is 120.) A representation of the force (pressure) that blood exerts on the walls of the blood pressure as it passes through them. If more than one number is found, choose the lowest (worst).
Ischemic	Ischemia literally means a restriction or reduction in blood supply. In this context it represents whether the cause of the heart failure is related to a reduction in the flow of blood to the heart. While the chart may not say ischemic heart disease, some other terms to indicate that the cause of the heart failure is ischemia would include: history of myocardial infarction (abbreviated either h/o MI or just MI); coronary artery disease (CAD), a record of coronary artery bypass grafting (CABG), or a notation that the patient has had previous coronary intervention (PCI = percutaneous coronary intervention, stents placed). Note if the chart does not indicate ischemic and/or the terms indicated above, the patient is considered non-ischemic. This is a present/absent checkbox.

NOTE, FOR MEDICATIONS WE COUNT ALL THE MEDS THE PATIENT IS ON AT THE TIME OF SCREENING, BEFORE THEIR OUTPATIENT VISIT ENDS. IN OTHER WORDS IF A MEDICATION IS DISCONTINUED ON THE DAY YOU ARE SCREENING THE PATIENT, YOU WOULD STILL COUNT IT HAS A CURRENT MEDICATION.

ACE-I	A class of medications known as Angiotension Converting Enzyme Inhibitors. This is a present/absent checkbox.
Beta-Blocker	A class of medications used for the management of cardiac arrhythmias, to protect the heart after myocardial infarction (heart attack), and hypertension. This is a present/absent checkbox.
ARB	Angiotension Receptor Blocker - used for controlling high blood pressure, treating heart failure, and preventing kidney failure in people with diabetes or high blood pressure. This is a present/absent checkbox. Medications in this category may include: candesartan (Atacand) eprosartan (Teveten) irbesartan (Avapro)

	telmisartan (Micardis) valsartan (Diovan) losartan (Cozaar) olmesartan (Benicar).
Statin	A class of medications used to lower cholesterol in patients with heart disease. This is a present/absent checkbox
Allopurinol	Used extensively for the treatment of gout, has been shown to improve endothelial dysfunction in heart failure. This is a present/absent checkbox. Includes Allopurinol (brand names: Lopurin, Zyloprim).
Aldosterone Blocker	Diuretic drugs which antagonize the action of aldosterone at mineralocorticoid receptors. This group of drugs is often used as adjunctive therapy, in combination with other drugs, for the management of chronic heart failure. This is a present/absent checkbox.
Furosemide	A diuretic – a medication that increases urination. Also known as lasix. Note that this box asks for the total daily dose, which may need to be calculated. (e.g. 40mg tid = 120 mg daily) QOD = every other day QD = daily BID = twice daily TID = three times a day QID = 4 times a day
Bumetadine	A diuretic – a medication that increases urination. Note that this is the total daily dose, which may need to be calculated. Also known as Bumex.
Torsemide	A diuretic – a medication that increases urination Note that this is the total daily dose, which may need to be calculated. Also known as demadex.
Metolazone	A diuretic – a medication that increases urination Note that this is the total daily dose, which may need to be calculated. Also known as zaroxolyn.
HCTZ	Hydrochlorothiazide. A diuretic – a medication that increases urination. Usually a multiple of 12.5 (e.g. 12.5, 25, etc) Also known as esidrix or microzide. May also be a combination medication. (see list). In this case, it is usually the last portion of the medication.

Hgb	Hemoglobin – the iron-containing oxygen-transport metalloprotein in red blood cells. Hemoglobin in the blood is what transports oxygen from the lungs to the rest of the body. Often found as part of the CBC (complete blood count). Normal is between 12-18, though will often be lower in chronically ill patients. If more than one value, choose the lowest. Additionally, it may be written in the chart in the shorthand below:   If no value is available use the default value. Note: if the value is available but is greater than a year old, use the value available. Only use the default value if there is no value at all.
% lymph	The percent of white blood cells that are lymphocytes. This is part of the differential in a CBC (CBC+PLTS+DIFF or CBC+DIFF). Be sure using the % lymph and not the absolute number. If no value is available use the default value. Note: if the value is available but is greater than a year old, use the value available. Only use the default value if there is no value at all.
Uric Acid	A bi-product of breakdown of proteins. High serum UA levels are a marker of poorer prognosis in patients with moderate to severe HF. A slightly unusual test, best found by searching for it under chemistry. If not available or value is greater than a year old at the time of screening, the investigators who created the model direct that we should use the following values, based on the patient's Heart Failure Class: Class Uric Acid 1 6.2 2 6.2 3 6.3 3A 6.5 3B 8.1 4 8.6

	(Note – if you use a version of the model other than that on the web, these may auto-populate the uric acid field.)
Total cholesterol	May be part of lipid panel. If more than one value available, use highest. If no value is available use the default value. Note: if the value is available but is greater than a year old, use the value available. Only use the default value if there is no value at all.
Sodium	An element in the body that is important in the regulation of water and fluids. May be low in heart failure. Found as part of routine chemical testing – so may be under "routine" "chemistry" or "Chem-6" or "chem.-7". Abbreviation is Na – so may be found this way as well. Additionally, it may be written in the chart in the shorthand below. If no value is available use the default value. Note: if the value is available but is greater than a year old, use the value available. Only use the default value if there is no value at all. 
QRS>120	This is a measure of one of the elements of the EKG. Look at the most recent EKG - at the top it will state the duration of the QRS. Do not need to check off, does not affect the model.
ICD vs. BiV ICD	This relates to whether the ICD is in one or both ventricles. If you can locate the ICD implant report, this is the easiest place to find this. However it may be in the outpatient or inpatient notes. If there is only a mention of "ICD" or "AICD" then check ICD. **THIS BOX IS VERY IMPORTANT AND IS EASY TO MISS! THIS DATA POINT DRAMATICALLY CHANGES THE SURVIVAL ESTIMATE.**

Medication List for the SHFM Model

Drug Name	Class	Notes
Accupril	ACE-I	
Accuretic 10/12.5 (containing Hydrochlorothiazide and quinapril)	HCTZ	Record actual dose
Accuretic 20/12.5 (containing Hydrochlorothiazide and quinapril)	HCTZ	Record actual dose
Accuretic 20/25 (containing Hydrochlorothiazide and quinapril)	HCTZ	Record actual dose
Acebutolol (Sectral)	Beta-Blocker	
Aceon	ACE-I	
Advicor	Statin	
Aldactazide	Aldosterone Blocker	
Aldactazide (containing Hydrochlorothiazide and Spironolactone)	HCTZ	Record actual dose
Aldactone	Aldosterone Blocker	
Aldoril (containing Hydrochlorothiazide and Methyldopa)	HCTZ	Record actual dose
Allopurinol	Allopurinol	
Aloprim	Allopurinol	
Alprenolol	Beta-Blocker	
Altace	ACE-I	
Altocor	Statin	
Altoprev	Statin	
Amturnide (containing Amlodipine, Hydrochlorothiazide, and aliskiren)	HCTZ	Record actual dose
Atacand	ARB	
Atacand HCT 16/12.5 (containing Hydrochlorothiazide and candesartan)	HCTZ	Record actual dose
Atacand HCT 32/12.5 (containing Hydrochlorothiazide and candesartan)	HCTZ	Record actual dose
Atacand HCT 32/25 (containing Hydrochlorothiazide and candesartan)	HCTZ	Record actual dose
Atenolol (Tenormin)	Beta-Blocker	
Atorvastatin	Statin	
Avalide 150/12.5 (containing Hydrochlorothiazide and irbesartan)	HCTZ	Record actual dose
Avalide 300/12.5 (containing Hydrochlorothiazide and irbesartan)	HCTZ	Record actual dose

Avalide 300/25 (containing Hydrochlorothiazide and irbesartan)	HCTZ	Record actual dose
Avapro	ARB	
Baycol	Statin	
Benazepril (Lotensin)	ACE-I	
Benicar	ARB	
Benicar HCT 20/12.5 (containing Hydrochlorothiazide and olmesartan)	HCTZ	Record actual dose
Benicar HCT 40/12.5 (containing Hydrochlorothiazide and olmesartan)	HCTZ	Record actual dose
Benicar HCT 40/25 (containing Hydrochlorothiazide and olmesartan)	HCTZ	Record actual dose
Betapace	Beta-Blocker	
Betaxolol	Beta-Blocker	
Bisoprolol (Zebeta)	Beta-Blocker	
Blocarden	Beta-Blocker	
Bucindolol	Beta-Blocker	
Bumetanide	Bumetadine	Record actual dose
Bumex	Bumetadine	Record actual dose
Caduet	Statin	
candesartan (Atacand)	ARB	
Canrenone (canrenoate potassium) ---?	Aldosterone Blocker	
Canreonate potassium	Aldosterone Blocker	
Capoten	ACE-I	
Capozide 25/15 (containing Captopril and Hydrochlorothiazide)	HCTZ	Record actual dose
Capozide 25/25 (containing Captopril and Hydrochlorothiazide)	HCTZ	Record actual dose
Capozide 50/15 (containing Captopril and Hydrochlorothiazide)	HCTZ	Record actual dose
Capozide 50/25 (containing Captopril and Hydrochlorothiazide)	HCTZ	Record actual dose
Captopril	ACE-I	
Carteolol	Beta-Blocker	
Carvedilol (Coreg, Coreg CR)	Beta-Blocker	
Celiprolol	Beta-Blocker	
Cerivastatin	Statin	
Compactin	Statin	

Coreg	Beta-Blocker	
Coreg CR	Beta-Blocker	
Corgard	Beta-Blocker	
Corzide	Beta-Blocker	nadolol and bendroflumethiazide (B-blocker and diuretic)
Coversyl	ACE-I	
Cozaar	ARB	
Crestor	Statin	
Demadex	Torsemide	Record actual dose
Diovan	ARB	
Diovan HCT 160/12.5 (containing Hydrochlorothiazide and valsartan)	HCTZ	Record actual dose
Diovan HCT 160/25 (containing Hydrochlorothiazide and valsartan)	HCTZ	Record actual dose
Diovan HCT 320/12.5 (containing Hydrochlorothiazide and valsartan)	HCTZ	Record actual dose
Diovan HCT 320/25 (containing Hydrochlorothiazide and valsartan)	HCTZ	Record actual dose
Diovan HCT 80/12.5 (containing Hydrochlorothiazide and valsartan)	HCTZ	Record actual dose
Diuretic Ap-Es (containing Hydralazine, Hydrochlorothiazide, and Reserpine)	HCTZ	Record actual dose
Dutoprol 100/12.5 (containing Hydrochlorothiazide and Metoprolol)	HCTZ	Record actual dose
Dutoprol 25/12.5 (containing Hydrochlorothiazide and Metoprolol)	HCTZ	Record actual dose
Dutoprol 50/12.5 (containing Hydrochlorothiazide and Metoprolol)	HCTZ	Record actual dose
Enalapril (Vasotec/Renitec)	ACE-I	
Eplerenone (Inspra)	Aldosterone Blocker	
eprosartan (Teveten)	ARB	
Esidrix	HCTZ	Record actual dose
Esimil (containing Guanethidine and Hydrochlorothiazide)	HCTZ	Record actual dose
Esmolo	Beta-Blocker	
Exforge HCT 10/160/12.5 (containing Amlodipine, Hydrochlorothiazide, and valsartan)	HCTZ	Record actual dose
Exforge HCT 10/160/25 (containing Amlodipine, Hydrochlorothiazide, and valsartan)	HCTZ	Record actual dose
Exforge HCT 10/320/25 (containing Amlodipine, Hydrochlorothiazide, and valsartan)	HCTZ	Record actual dose
Exforge HCT 5/160/12.5 (containing Amlodipine, Hydrochlorothiazide, and valsartan)	HCTZ	Record actual dose

Exforge HCT 5/160/25 (containing Amlodipine, Hydrochlorothiazide, and valsartan)	HCTZ	Record actual dose
Fluvastatin	Statin	
Fosinopril (Monopril)	ACE-I	
Furosemide	Furosemide	Record actual dose
HCTZ	HCTZ	Record actual dose
HHR (containing Hydralazine, Hydrochlorothiazide, and Reserpine)	HCTZ	Record actual dose
Hydrap-ES (containing Hydralazine, Hydrochlorothiazide, and Reserpine)	HCTZ	Record actual dose
Hydrochlorothiazide	HCTZ	Record actual dose
Hydropres-25 (containing Hydrochlorothiazide and Reserpine)	HCTZ	Record actual dose
Hydropres-50 (containing Hydrochlorothiazide and Reserpine)	HCTZ	Record actual dose
Hydro-Reserp (containing Hydrochlorothiazide and Reserpine)	HCTZ	Record actual dose
Hydroserp (containing Hydrochlorothiazide and Reserpine)	HCTZ	Record actual dose
Hydroserpine #1 (containing Hydrochlorothiazide and Reserpine)	HCTZ	Record actual dose
Hydroserpine (containing Hydrochlorothiazide and Reserpine)	HCTZ	Record actual dose
Hyzaar 100/12.5 (containing Hydrochlorothiazide and Losartan)	HCTZ	Record actual dose
Hyzaar 100/25 (containing Hydrochlorothiazide and Losartan)	HCTZ	Record actual dose
Hyzaar 50/12.5 (containing Hydrochlorothiazide and Losartan)	HCTZ	Record actual dose
Imidapril (Tanatril)	ACE-I	
Inderal	Beta-Blocker	
Inderal LA	Beta-Blocker	
Inderide	Beta-Blocker	propranolol HCI and hydrochlorothiazide(B-blocker and diuretic)
Inderide 40/25 (containing Hydrochlorothiazide and Propranolol)	HCTZ	Record actual dose
Inderide 80/25 (containing Hydrochlorothiazide and Propranolol)	HCTZ	Record actual dose
Inderide LA	Beta-Blocker	propranolol HCI and hydrochlorothiazide (B-blocker and diuretic)
Innopran	Beta-Blocker	
Inspra	Aldosterone Blocker	

irbesartan (Avapro)	ARB	
Labetalol (Trandate)	Beta-Blocker	
Lasix	Furosemide	Record actual dose
Lescol	Statin	
Lescol XL	Statin	
Lipex	Statin	
Lipitor	Statin	
Lipobay	Statin	
Lipostat	Statin	
Lisinopril (Listril/Lopril/Novatec/Prinivil/Zestril)	ACE-I	
Listril	ACE-I	
Livalo, Pitava	Statin	
Lopressor	Beta-Blocker	
Lopressor HCT	Beta-Blocker	metoprolol tartrate and hydrochlorothiazide (B-blocker and diuretic)
Lopressor HCT 100/25 (containing Hydrochlorothiazide and Metoprolol)	HCTZ	Record actual dose
Lopressor HCT 100/50 (containing Hydrochlorothiazide and Metoprolol)	HCTZ	Record actual dose
Lopressor HCT 50/25 (containing Hydrochlorothiazide and Metoprolol)	HCTZ	Record actual dose
Lopril	ACE-I	
Lopurin	Allopurinol	
losartan (Cozaar)	ARB	
Lotensin	ACE-I	
Lotensin HCT 10/12.5 (containing Hydrochlorothiazide and benazepril)	HCTZ	Record actual dose
Lotensin HCT 20/12.5 (containing Hydrochlorothiazide and benazepril)	HCTZ	Record actual dose
Lotensin HCT 20/25 (containing Hydrochlorothiazide and benazepril)	HCTZ	Record actual dose
Lotensin HCT 5/6.25 (containing Hydrochlorothiazide and benazepril)	HCTZ	Record actual dose
Lovastatin	Statin	
Mallopress (containing Hydrochlorothiazide and Reserpine)	HCTZ	Record actual dose
Marpres (containing Hydralazine, Hydrochlorothiazide, and Reserpine)	HCTZ	Record actual dose

Maxzide (containing Hydrochlorothiazide and Triamterene)	HCTZ	Record actual dose
Metolazone	Metolazone	Record actual dose
Metoprolol (Lopressor, Torprol XL)	Beta-Blocker	
Mevacor	Statin	
Mevastatin	Statin	
mexrenoate potassium	Aldosterone Blocker	
Mexrenone (mexrenoate potassium)	Aldosterone Blocker	
Micardis	ARB	
Micardis-HCT 40/12.5 (containing Hydrochlorothiazide and telmisartan)	HCTZ	Record actual dose
Micardis-HCT 80/12.5 (containing Hydrochlorothiazide and telmisartan)	HCTZ	Record actual dose
Micardis-HCT 80/25 (containing Hydrochlorothiazide and telmisartan)	HCTZ	Record actual dose
Microzide	HCTZ	Record actual dose
Moduretic 5-50 (containing Amiloride and Hydrochlorothiazide)	HCTZ	Record actual dose
Monopril	ACE-I	
Monopril-HCT 10/12.5 (containing Fosinopril and Hydrochlorothiazide)	HCTZ	Record actual dose
Monopril-HCT 20/12.5 (containing Fosinopril and Hydrochlorothiazide)	HCTZ	Record actual dose
Nadalol (Corgard)	Beta-Blocker	
Nadolol	Beta-Blocker	
Nebivolol	Beta-Blocker	
Novatec	ACE-I	
olmesartan (Benicar).	ARB	
Oreticyl 25 (containing Hydrochlorothiazide and deserpidine)	HCTZ	Record actual dose
Oreticyl 50 (containing Hydrochlorothiazide and deserpidine)	HCTZ	Record actual dose
Oreticyl Forte (containing Hydrochlorothiazide and deserpidine)	HCTZ	Record actual dose
Penbutolol	Beta-Blocker	
Perindopril (Coversyl/Aceon)	ACE-I	
Pindolol	Beta-Blocker	
Pitavastatin	Statin	
Pitavastatin	Statin	
Pravachol	Statin	

Pravastatin	Statin	
Prinivil	ACE-I	
Prinzide (containing Hydrochlorothiazide and Lisinopril)	HCTZ	Record actual dose
Propranolol (Inderal, Inderal LA, Innopran XL)	Beta-Blocker	
prorenoate potassium	Aldosterone Blocker	
Prorenone (prorenoate potassium)-----?	Aldosterone Blocker	
Purinol	Allopurinol	
Quinapril (Accupril)	ACE-I	
Quinaretic 10/12.5 (containing Hydrochlorothiazide and quinapril)	HCTZ	Record actual dose
Quinaretic 20/12.5 (containing Hydrochlorothiazide and quinapril)	HCTZ	Record actual dose
Quinaretic 20/25 (containing Hydrochlorothiazide and quinapril)	HCTZ	Record actual dose
Ramace	ACE-I	
Ramipril (Altace/Tritace/Ramace/Ramiwin)	ACE-I	
Ramiwin	ACE-I	
Renitec	ACE-I	
Rosuvastatin	Statin	
Sectral	Beta-Blocker	
Selektine	Statin	
Ser-Ap-Es (containing Hydralazine, Hydrochlorothiazide, and Reserpine)	HCTZ	Record actual dose
Serathide (containing Hydralazine, Hydrochlorothiazide, and Reserpine)	HCTZ	Record actual dose
Serpazide (containing Hydralazine, Hydrochlorothiazide, and Reserpine)	HCTZ	Record actual dose
Serpex (containing Hydralazine, Hydrochlorothiazide, and Reserpine)	HCTZ	Record actual dose
Simcor	Statin	
Simvastatin	Statin	
Simvastatin+Ezetimibe	Statin	
Sotalol (Betapace)	Beta-Blocker	
Spironolactone (Aldactone, Aldactazide)	Aldosterone Blocker	
Spironolactone Plus (containing Hydrochlorothiazide and Spironolactone)	HCTZ	Record actual dose
Tanatril	ACE-I	
Tekturna HCT 150/12.5 (containing Hydrochlorothiazide and aliskiren)	HCTZ	Record actual dose

Tekturna HCT 150/25 (containing Hydrochlorothiazide and aliskiren)	HCTZ	Record actual dose
Tekturna HCT 300/12.5 (containing Hydrochlorothiazide and aliskiren)	HCTZ	Record actual dose
Tekturna HCT 300/25 (containing Hydrochlorothiazide and aliskiren)	HCTZ	Record actual dose
telmisartan (Micardis)	ARB	
Tenoretic	Beta-Blocker	atenolol and chlorthalidone (B-blocker and diuretic)
Tenormin	Beta-Blocker	
Teveten	ARB	
Teveten HCT (containing Hydrochlorothiazide and eprosartan)	HCTZ	Record actual dose
Timolide	Beta-Blocker	timolol maleate and hydrochlorothiazide (B-blocker and diuretic)
Timolide (containing Hydrochlorothiazide and Timolol)	HCTZ	Record actual dose
Timolol	Beta-Blocker	
Timolol (Blocardren)	Beta-Blocker	(NOTE: timolol may also be EYE DROPS – sometimes noted as gtt or gtts or ophthalmic – this shouldn't be included)
Toprol XL	Beta-Blocker	
Torsemide	Torsemide	Record actual dose
Torvast	Statin	
Trandate	Beta-Blocker	
Tribenzor 20/5/12.5 (containing Amlodipine, Hydrochlorothiazide, and olmesartan)	HCTZ	Record actual dose
Tribenzor 40/10/12.5 (containing Amlodipine, Hydrochlorothiazide, and olmesartan)	HCTZ	Record actual dose
Tribenzor 40/10/25 (containing Amlodipine, Hydrochlorothiazide, and olmesartan)	HCTZ	Record actual dose
Tribenzor 40/5/12.5 (containing Amlodipine, Hydrochlorothiazide, and olmesartan)	HCTZ	Record actual dose
Tribenzor 40/5/25 (containing Amlodipine, Hydrochlorothiazide, and olmesartan)	HCTZ	Record actual dose
Tri-Hydroserpine (containing Hydralazine, Hydrochlorothiazide, and Reserpine)	HCTZ	Record actual dose
Tritace	ACE-I	
Uni Serp (containing Hydralazine, Hydrochlorothiazide, and Reserpine)	HCTZ	Record actual dose

Unipres (containing Hydralazine, Hydrochlorothiazide, and Reserpine)	HCTZ	Record actual dose
Uniretic 15/12.5 (containing Hydrochlorothiazide and moexipril)	HCTZ	Record actual dose
Uniretic 15/25 (containing Hydrochlorothiazide and moexipril)	HCTZ	Record actual dose
Uniretic 7.5/12.5 (containing Hydrochlorothiazide and moexipril)	HCTZ	Record actual dose
valsartan (Diovan)	ARB	
Vaseretic (containing Enalapril and Hydrochlorothiazide)	HCTZ	Record actual dose
Vasotec	ACE-I	
Vytorin	Statin	
zaroxolyn	Metolazone	Record actual dose
Zebeta	Beta-Blocker	
Zestoretic 10/12.5 (containing Hydrochlorothiazide and Lisinopril)	HCTZ	Record actual dose
Zestoretic 20/12.5 (containing Hydrochlorothiazide and Lisinopril)	HCTZ	Record actual dose
Zestoretic 20/25 (containing Hydrochlorothiazide and Lisinopril)	HCTZ	Record actual dose
Zestril	ACE-I	
Ziac	Beta-Blocker	bisoprolol fumarate and hydrochlorothiazide (B-blocker and diuretic)
Ziac 10/6.25 (containing Bisoprolol and Hydrochlorothiazide)	HCTZ	Record actual dose
Ziac 2.5/6.25 (containing Bisoprolol and Hydrochlorothiazide)	HCTZ	Record actual dose
Ziac 5/6.25 (containing Bisoprolol and Hydrochlorothiazide)	HCTZ	Record actual dose
Zocor	Statin	
Zofenopril	ACE-I	
Zyloprim	Allopurinol	

Watchlist

The “Watchlist” is a way of determining if patients who are not initially eligible become eligible over the course of the study. A patient should be kept on the Watchlist if they are a soft failure. **Soft failures include**: Not meeting all of the outpatient or inpatient criteria. These patients are re-screened every six months or more depending on whether or not they border the eligibility criteria **Hard failures include**: Has a VAD, Not fluent in English, No Reliable Access to a Phone, Physician Refused to Let You Approach the Patient, Patient Refused, Patient Died between Screening and Approach, and Patient Unable to Provide Informed Consent. If a patient has not been seen at a site facility, inpatient or outpatient, for 18 months or longer, complete a WDM14 selecting “Did not meet eligibility criteria” and then “Inpatient/Outpatient criterion not met.” Ensure that these patients are marked in the screening log in a way that they will be re-screened and not skipped if they are seen inpatient or outpatient at a site’s facility. If the patient returns to a site facility, inpatient or outpatient, invalidate the previously completed screen failure. By the end of enrollment, all screened patients should be enrolled in the study or have a WDM14 completed.

The first page of WDM90 – The Eligibility Screening Tool has a grid that can serve as an ongoing assessment for patients. Once a patient becomes eligible, the last line on page one is completed. Otherwise the patient is rescreened at the 6 month mark to determine if there is a change in eligibility. As a reminder, some patients may be screened before the six month mark if they border eligibility; however, any screening before the six month mark should be treated as ‘one screening’.

If a patient becomes ineligible, the last line on page one is completed.
Each site should keep a running list of Watchlist patients, to make it easier to determine when the best screening should be.

The data from the Watchlist grid is never ultimately recorded in the EDC. However a final designation is assigned for every patient, and either WDM14 – Screen Failure (either not eligible or refusal) or WDM08 – Eligibility Confirmation (for those patients enrolled) is completed for EVERY screened patient. Some of the data collected on WDM90, and the “surprise question” is entered into the EDC as part of WDM10 – Baseline Chart Abstraction.

Exclusion Criteria

Exclusion criteria for the study are essentially the opposite of the entry criteria. For patients:

- Being under age 18, not having an ICD
- Not having appropriate clinical criteria (being too well to be considered appropriate for a conversation about device deactivation)
- Having a VAD
- Not having access to a phone

- Not being able to speak/understand English
- Not being able to sign informed consent

Note that patients who do not have a caregiver ARE STILL ELIGIBLE. This is a change from the grant application. In other words, not having a caregiver is NOT an exclusion criterion.

Remember: As of August 1, 2012, being a candidate for VAD or transplant is no longer an exclusion criteria.

Exclusion criteria for caregivers:

- Being under age 18
- Not having access to a phone
- Not being able to speak/understand English
- Not being able to sign informed consent

Caregivers are not enrolled without a patient. That is, if a patient can't be consented, the caregiver is not enrolled. Only one caregiver is enrolled per patient. If a caregiver drops out of the study, no additional caregiver is enrolled.

Note if a patient is terminated from the study for the following reasons: Patient Death, Patient Withdrawal of Consent, Patient Can no Longer Participate, or Lost to Follow-up, we can continue to follow the caregiver so long and they are willing to participate in the study. If however, the patient is terminated for the following reason: Clinician Decision to Withdraw Patient, the caregiver is automatically withdrawn.

Procedures for Enrolling Patients

The flow diagram for enrollment procedures for patients is found in section I of the MOP.

Once a patient has been determined to be eligible, the following steps are taken:

FOR OUTPATIENT:

- The local RC determines when the patient is coming to clinic.
- At the end of the clinic appointment, a member of the primary clinical team caring for the patient (may be MD, NP, or RN in clinic) approaches patient and states they are "Eligible for a study relating to quality of life in patients with Heart Failure. Would you like to hear more about the study?"
- If yes – the local RC enters the clinic room (or takes the patient to another private location) and explains the study and answers the patient's questions.
- As part of the informed consent, the local RC asks the patient to explain the study using his/her words so that the RC can assure the patient understands the study.
- The local RC then has the patient sign the informed consent.

- The local RC then signs the consent form and makes sure that the TIME NEXT TO THE RC SIGNATURE IS AFTER THE PATIENT'S SIGNATURE.

FOR INPATIENT:

- The local RC determines the patient's location in the hospital.
- Before approaching the patient, a member of the primary clinical team caring for the patient (may be MD, NP, or RN in clinic) approaches patient and states they are "Eligible for a study relating to quality of life in patients with Heart Failure. Would you like to hear more about the study?"
- If yes – the local RC approaches the patient in their room (or takes the patient to another private location) and explains the study and answers the patient's questions.
- As part of the informed consent, the local RC asks the patient to explain the study using his/her words so that the RC can assure the patient understands the study.
- The local RC then has the patient sign the informed consent.
- The local RC then signs the consent form and makes sure that the TIME NEXT TO THE RC SIGNATURE IS AFTER THE PATIENT'S SIGNATURE.

When a patient signs the informed consent form, a copy of the informed consent form is placed in the patient's outpatient/inpatient medical record (either a hard copy or a scanned document in the EMR), along with a copy of WDM92 – Patient Informed Consent Documentation Template.

A copy of the consent form is given to the patient. The local RC keeps THE ORIGINAL copy of the consent form on file. (The ORIGINAL consent is never given to a subject.) A copy of the consent form is faxed to the central RC at Mount Sinai (646-537-8556). Note that by completing WDM08 – Patient Eligibility Confirmation, you are certifying that you completed the informed consent process appropriately.

The following forms are completed by the local RC for every patient enrollment: WDM01, WDM03, WDM08, WDM07, WDM10, and WDM51. WDM19 is also completed in full for any patient that is **NOT** a VAD/Transplant candidate. If the patient **IS** a VAD/Transplant candidate, the patient is monitored over the course of the study to see if there is a status change. Ultimately every patient will have a WDM19 completed by the end of the study. These packets should be taken to the potential enrollment with the local RC in the event that the patient is able to complete the baseline forms immediately. (WDM10 – the baseline medical record abstraction and WDM19- VAD/Transplant Screening tool, do not need to be taken to the enrollment session). Alternatively, the RC can complete only WDM 03 – the patient contact form – and begin WDM 01 (as this creates the study ID) and then administer the remaining forms over the phone.

When the local RC returns to his/her office, WDM01 should be initiated in the EDC immediately, as this form generates the study ID, a number which must be placed on all forms. The study ID takes the following form:

ABC-X-ZZZ

Where:

ABC = patient initials

X=Study Site

1=Mount Sinai
2=Mayo
3=Montefiore
4=OHSU (no longer collaboratingon this study)
5=Penn
6=University of Colorado Denver
7= Yale University

Z= a unique sequential number, starting at 001

Each site should keep their own list of patient IDs and patient identities. This will allow a back-up system should there be a discrepancy between subject ID and identity later in the study. This can be kept in a simple Excel spreadsheet with the following headings: ID, Name, and Date of Study Entry. This file contains identifiable information and local protection protocols should be followed to maintain the security of the data.

WDM08 – Patient Eligibility Confirmation

The purpose of the patient eligibility confirmation is to certify that the patient meets all eligibility criteria. This document states that the local RC certifies the subject meets eligibility /exclusion criteria and is needed for future local or external audits. The form also contains a certification statement attesting that the RC completed the informed consent process according to protocol.

WDM01 – Enrollment/Demographics – Patient

The enrollment/demographics form is an important form as it generates the study ID. Even if the baseline patient data collection isn't completed at the time of study enrollment, items 1-6 should be completed the same day as enrollment, because these data are important identifiers that are used to generate the ID and/or clarify any future discrepancies in the data collection.

Remember that this form contains PHI and must be treated in a secure manner at all times.

Specific instructions for completing WDM01 are as follows:

- Question 6 – This question should be asked as follows:
  "Do you consider yourself to be Hispanic or Latino?"
- Question 7 – Racial Category

  - These categories reflect current NIH categories. Note that a patient may choose more than one race. A patient who self identifies as more than one race is not "other"
  - This question should be asked as follows: "What do you consider to be your race?" If the patient does not use one of the racial categories, you may read the list of categories to him/her.
- Question 8 – Marital Status
  - This question should be asked as: "What is your current marital status? Are you…" then read the categories (do not read "Don't know" or "Refusal").
- Question 9 is asked as "Do you currently live alone or with someone?"
- Question 10 is only answered for those patients who do not live alone (the EDC will only allow a response if Question 10 is answered as "lives with someone").
- Question 11 is asked as "What is the highest degree or level of education you completed?"
- Question 13 asks if the patient was previously screened. Due to the new changes in eligibility criteria, there may be patients that were previously screened and were ineligible and became screen failures but are now eligible. If this is the case, check off 'Yes' to previously screened. If the patient was never a screened in the sense that they were never a screen failure, check off 'No'.

WDM03 – Patient Contact Information

WDM03 is used to contact the patient for all follow up interviews. For this reason it is very important that the local RC tries to get both a primary and secondary contact number for the patient. The address will be used to mail question guides to the patient that will be used in subsequent interviews, so the patient can follow along with the phone interview. This information is also used to mail the incentives, newsletters, and any correspondence to the subject.

WDM07 – Patient Report of Comorbidity

The patient report of comorbidity is the patient version of the Charlson Comorbidity scale.[7-8] It can be completed following the completion of the baseline interview as the answers can be derived from the questionnaire (WDM51).

The guide below walks the interviewer through the comorbidity questions:

Now I am going to read you a list of medical conditions. Please tell me if you have ever been told that you have or have been diagnosed with the following conditions:

1. Had a heart attack?

2. Had an operation to unclog or bypass the arteries in your legs?

3. Had a stroke, cerbrovascular accident, blood clot, bleeding in the brain, or transient ischemic attack?

IF YES ⟶ Had difficulty moving an arm or leg as a result of the [number 3]?

4. Had asthma?

IF YES ⟶ Do you take medications for your asthma?

5. Had emphysema, chronic bronchitis, or chronic obstructive lung disease?

IF YES ⟶ Do you take medications for your lung disease?

6. Have you ever had stomach problems or peptic ulcer disease?

IF YES ⟶ Was this condition diagnosed by either endoscopy, where a doctor looks at the stomach through a scope or an upper gi series or barium swallow where you would have swallowed chalky dye and then have x-rays taken?

7. Have Alzheimer's disease, or any other form of dementia?

8. Have cirrhosis or serious liver damage?

9. Have diabetes or high blood sugar?

IF YES ⟶ Do you take medications for your diabetes?
⟶ Does the diabetes cause problems with your kidneys or eyes?

10. Have problems with your kidneys? Specifically, did you ever have poor kidney function, need dialysis, or receive a kidney transplant?

11. Have rheumatoid arthritis, lupus (systemic lupus erythematosus) or polymalgia rheumatica?

IF RHEUMATOID ARTHIRITIS:
Do you take medications DAILY for your Rheumatoid Arthritis?

12. Have lymphoma?
NOTE TO INTERVIEWER: If need definition: a type of cancer which starts in the lymph nodes. Note to Interviewer: Lymphoma is different *than a cancer which* spread *to the lymph nodes.*

13. Have leukemia or polycythemia vera?

NOTE TO INTERVIEWER: If definition of polycythemia vera is needed, use the following: *Polycythemia vera is a condition where the body makes too many red blood cells – that is –where the body has too much blood. This is* not *the same as anemia, where the body has* not enough *blood.*

14. Have cancer, other than skin cancer, leukemia, or lymphoma?

IF YES ⟶ Had it spread to other parts of your body?

⟶ Had you had it for more than 5 years?

15. Have HIV/AIDS?

Note: This list should be taken with you to interviews to assure uniformity in the ways these questions are asked across sites.

WDM19- VAD/Heart Transplant Screening Tool
At All Sites:

A VAD/Heart Transplant screening tool is completed for every subject at some point in during the duration of the study. If the patient is **NOT** a VAD/Heart Transplant candidate at time of enrollment, this form is completed following consent. Use the WDM19 form located in the baseline folder in the EDC. In some cases, a patient may not be a VAD/transplant candidate at the time of enrollment but may become a candidate for these therapies down the line. Patients that are **not** candidates for these therapies should be screened on a quarterly basis to determine if there has been a status change. If, there has, complete a new WDM19 under the event driven folder.

If the patient **IS** a VAD/Heart Transplant candidate, then the RC should contact the patient's enrolled clinician on a quarterly basis and/or on the **fifth** day of any hospitalization the patient has, to determine if there has been a status change. If the clinician indicates that the patient became too ill or is no longer a candidate for these therapies, the RC may complete WDM19 under the event driven folder in the EDC and continue monitoring subjects as they would non-VAD/Heart Transplant candidates. If the patient receives a heart transplant, the RC should complete this form along with WDM06-subject termination form. If the patient dies, the RC should complete this form along with WDM06-subject termination form and WDM05-Subject mortality form. If there is never a status change, this form is completed at the end of the study.

*If the patient is hospitalized for less than five days, the RC should not correspond with the clinician as hospitalizations less than five days in length will unlikely result in a status change.

VAD/Heart transplant Participants at Non-intervention Sites:

At non-intervention sites, VAD/Heart Transplant candidacy does not change how the protocol is run. In other words, VAD/Heart transplant candidates are treated in the same manner as non-VAD/Heart transplant candidates. RCs still complete all baseline assessments, follow-up assessments and chart abstractions.

VAD/Heart transplant Participants at Intervention Sites:

At intervention sites, we do not begin reminders to clinicians until the patient is no longer a VAD/Heart transplant candidate. In other words, if a patient is initially a VAD/Heart transplant candidate, the RCs at intervention sites should NOT begin clinician reminders until the clinician has advised them that the patient became too ill or is no longer a candidate for these therapies. If that is the case, the RC may complete WDM19 at that time and begin sending reminders as they would for non- VAD/Heart transplant candidates. If the patient receives a heart transplant, the RC should complete this form along with WDM06. If the patient dies, the RC should complete this form along with WDM06 and WDM05. If there is never a status change, this form is completed at the end of the study.

Note this form is not completed if the patient receives a VAD nor is receiving a VAD a study endpoint. If the patient goes on to receive a VAD as Destination Therapy (DT) then reminders may begin. If the patient goes on to receive a VAD as Bridge to Transplant (BTT), we do not begin reminders till there is a change in status.

Regardless of candidacy for these therapies and with the exception of sending reminders, RCs at intervention sites still complete all baseline assessments, follow-up assessments and chart abstractions for these patients as they would for non-VAD/Heart Transplant Candidates.

Procedure for Enrolling Caregivers

The study flow diagram for the caregiver enrollment is in section I of the MOP. Once the patient has been enrolled, he/she is asked if there is a primary family caregiver who plays a significant/important role in his/her healthcare. The patient is then asked if the caregiver can be contacted for the study as well. If the caregiver is present, he/she is approached at the same time the patient is enrolled. If the caregiver is not present, the local RC asks the patient if there is a phone number so the caregiver can be contacted.

When Caregiver Present

- The caregiver is approached in a private setting (clinic room/inpatient room or taken to a private area) and the local RC explains the study to the caregiver. The local RC reviews the informed consent document with the

caregiver and answers the caregiver's questions. The caregiver may be consented in the same room as the patient if they are in agreement to do so. Note however caregiver interviews should never be conducted when the patient is present as this may interfere with responses.

- As part of the informed consent, the local RC asks the caregiver to explain the study using his/her words so that the RC can assure the caregiver understands the study.
- The local RC then has the caregiver sign the informed consent.
- The local RC then signs the consent form and makes sure that the TIME NEXT TO THE RC SIGNATURE IS AFTER THE CAREGIVER'S SIGNATURE.
- The local RC gives the caregiver a copy of the consent form.

When Caregiver Not Present

The local RC gets the contact information for the caregiver, and contacts the caregiver to see if he/she is interested in participating. The local RC attempts to make an appointment for the caregiver to come in and complete the signed consent process in person. If the caregiver is not able to come in person:

- The local RC gets the caregiver's address where express mail can be delivered.
- The local RC calls the PM at Mount Sinai and tells her that a copy of the LOCAL consent should be sent to the caregiver via express mail.
- The PM mails a copy of the local consent to the caregiver. The package contains a self-addressed stamped envelope (SASE) that has the address of the local RC.
- The local RC calls the caregiver and walks him/her through the consent over the phone.
- As part of the informed consent, the local RC asks the caregiver to explain the study using his/her words so that the RC can assure the caregiver understands the study
- The local RC then has the caregiver sign the informed consent.
- The caregiver returns the consent to the local RC.
- The local RC then signs the consent form – using the CURRENT date and time.
- The local RC then mails a copy of the signed consent form to the caregiver (now with both signatures on it). The local RC includes a copy of the caregiver interview guide in the envelope. If the caregiver has a valid email address and prefers this method of delivery, a copy of the signed consent and/or guide may also be emailed to the caregiver.

  Note: If a caregiver does not return the signed informed consent within 5 to 7 business days, the local RC should follow up with the caregiver to see if it was returned. The local RC may contact the caregiver up to 3 times Up to three times meaning successful contact where you actually speak with the caregiver over the phone). If the local RC does not receive the informed consent following the third communication with the caregiver, the local RC can classify the caregiver as a 'Refusal'. The patient is still

eligible for the study as caregiver enrollment is not a condition for enrollment.

If your IRB allows an oral informed consent process, you should follow your local IRB process on oral consenting. Even if the consent is oral, a form must be used to document that oral consent was obtained.

Regardless of how the caregiver informed consent process is completed:
The local RC keeps THE ORIGINAL copy of the consent form on file. (The ORIGINAL consent is never given to a subject.) A copy of the caregiver consent form is faxed to the central RC at Mount Sinai (646-537-8556).

WDM13 – Caregiver Eligibility Confirmation

The purpose of the caregiver eligibility confirmation is to certify that the caregiver meets all eligibility criteria. This document states that the local RC certifies the subject meets eligibility /exclusion criteria and is needed for future local or external audits. Note that by completing WDM13 caregiver eligibility confirmation, the RC attests that the appropriate consent protocol was followed when the caregiver was enrolled.

WDM02 – Enrollment/Demographics – Caregiver

The enrollment/demographics form is an important form as it generates the relationship between the patient and the caregiver. Even if all of the baseline caregiver data collection isn't completed at the time of study enrollment, items 1-5 should be completed the same day as enrollment, because these data are important identifiers that are used to generate the link between patient and caregiver. Remember that this form contains PHI and must be treated in a secure manner at all times.

Note that the caregiver is not given a unique ID but instead uses that of the patient ID. Additionally, only one caregiver should be enrolled per patient. In the event that a caregiver withdraws from the study, is lost to follow-up or dies, site coordinators should continue to collect data on the enrolled patient however a new caregiver should never be enrolled. This is especially important given that the caregiver ID is that of the patient (i.e. if an additional caregiver is inadvertently enrolled this makes data analysis difficult.)

Specific instructions for completing WDM02 are as follows:

- Question 5– This question should be asked as follows:
  "Do you consider yourself to be Hispanic or Latino?"
- Question 6 – Racial Category
  - These categories reflect current NIH categories. Note that a patient may choose more than one race. A patient who self identifies as more than one race is not "other"
  - This question should be asked as follows:

"What do you consider to be your race?" If the patient does not use one of the racial categories, you may read the list of categories to him/her.

- Question 7 – Marital Status
  - This question should be asked as: "What is your current marital status? Are you…" then read the categories (do not read "Don't know" or "Refusal").
- Question 8 is asked as "Do you currently live alone or with someone?"
- Question 10 is asked as "What is the highest degree or level of education you completed?"

WDM04 – Caregiver Contact Information

WDM04 is used to contact the caregiver for all follow up interviews. For this reason it is very important that the local RC tries to get both a primary and secondary contact number for the caregiver. The address will be used to mail question guides to the caregiver that will be used in subsequent interviews, so the caregiver can follow along with the phone interview. This information is also used to mail the incentives to the subject.

Screen Failures and Refusals

The same form (WDM 14) is used for screen failures and refusals of both patients and their caregivers.

Each site keeps a log of the screening failures. For patients, this log should contain the date the screening failure was entered into the EDC, screening failure ID, and the patient's name and MRN. For caregiver failures it should contain the date the screening failure was entered into the EDC, the ***patient*** ID for whom the caregiver is a screen failure, the caregiver name, and the name of the patient with whom the caregiver is associated. The reason this log is maintained is that at the next screening point it will be easier to determine who has already been screened and wasn't eligible as a way to reduce reviewing the same (ineligible or refusal) subject more than once. Screen failure IDs for patients are created at each site locally, as the name of the patient/caregiver is never entered into the EDC – only the screen failure form is entered. In this manner PHI about failure screens are never retained.

If a patient is a failure – no data are entered for caregiver. That is – for patient failure a caregiver form is **NOT** completed. Caregiver failures are linked to the patient by the patient ID.

The configuration for failed screening ***patient*** IDs is the same as for those enrolled, except no patient initials are incorporated. The screening failure ID takes the following form:

FX-ZZZZ

Where:

F = failed

X=Study Site

1=Mount Sinai

2=Mayo
3=Montefiore
4=OHSU (no longer collaborating on this study)
5=Penn
6=University of Colorado Denver
7=Yale University

Z= a unique sequential number, starting at 001

<u>If a patient fails the screen or refuses then no screen failure is created for the caregiver.</u>

WDM14 – Patient/Caregiver Screen Failure

The screen failure form is important because at the end of the study, it allows for an analysis of differences between patients who are enrolled vs. those who either failed the eligibility criteria or refused. It is also used to create the CONSORT diagram (Consolidated Standards of Reporting Trials), at the end of the trial demonstrating final allocation of all patients. Thus it is vitally important that a screen failure form be completed for every patient or caregiver who fails the screen or refuses. The explanation for specific parts of the WDM14 – Screening Failure Form follows.

- Question 6 – Patient failure/refusal
  - If the patient is a screen failure because they did not meet eligibility criteria, check one of the boxes. If a patient failed for more than one reason, <u>check the one highest on the list first</u>.
  - If a physician refused approach, the patient refused, or the local RC was never able to contact a patient after he/she became eligible, enter the parameters listed on the form. This allows a later analysis of how these individuals differed from those who were ultimately enrolled.
  - If a patient has not been seen at a site facility, inpatient or outpatient, for 18 months or longer, complete a WDM14 selecting "Did not meet eligibility criteria" and then "Inpatient/Outpatient criterion not met." If the patient returns to a site clinic, inpatient or outpatient, invalidate the previously completed screen failure. By the end of enrollment, all screened patients should be enrolled in the study or have a WDM14 completed.
  - Other Miscellaneous Ineligibility Reasons:
    - ICD explant: Select "Other" and specify.
    - Patient no longer being followed at clinic: Select "Inpatient/Outpatient criterion not met"

- Question 7 – Caregiver failure/refusal
  - The first box is used if the patient has no caregiver they believe is appropriate or involved in their healthcare. The second box is used if the patient has a caregiver but the patient will not allow the team to approach the caregiver. It is important to distinguish between these two and one should specifically ask "Is it because there is no

one involved in your care or is it that you do not want us to speak with him/her?" if this isn't clear in the conversation with the patient.

INVALIDATING OLD SCREEN FAILURE FORMS:

Reasons to invalidate an old screen failure form:

1. If a patient was a screen failure in the past because they were a VAD/Heart Transplant candidate and you are now re-screening them and they become a screen failure the **second time around** (i.e, physician refused approach, patient refused, never able to contact after eligible, patient received a heart transplant between screening and approach, patient died between screening, never able to contact after eligible, and/or simply the patient did not meet the other clinical criteria to become eligible in the second screening) create a new screen failure form and invalidate the old one. The reason for invalidation would be 'New screen failure form completed'.

2. If the patient was originally a screen failure and is now eligible for enrollment, invalidate the old screen failure form. The reason for invalidation would be 'patient enrolled'. On WDM01 make sure you check off 'Yes' to question 13.

Procedure for Enrolling Clinicians

Clinicians enrolled in the study are considered research subjects, and the forms relating to their data are considered research documents subjected to the same human subjects regulations as other documents in this study.

Clinicians should be approached before the patient screening begins to assure that the clinician will allow access to his/her patients and will participate later with the assessment of the clinical criteria as needed. At intervention sites, the clinicians must be enrolled in the study before they attend the training session.

The procedure for enrolling clinicians is as follows:

- The local RC contacts the clinician and makes an appointment to discuss the study with him/her.
- The local RC meets with the clinician and explains the study to him/her and reviews the consent document
- As part of the informed consent, the local RC asks the clinician to explain the study using his/her words so that the RC can assure the clinician understands the study
- The local RC then has the clinician sign the informed consent.
- The local RC then signs the consent form and makes sure that the TIME NEXT TO THE RC SIGNATURE IS AFTER THE CLINICAN'S SIGNATURE.

When a clinician signs the informed consent form, a copy of the informed consent form is given to the clinician. The local RC keeps THE ORIGINAL copy of the consent form on file. (The ORIGINAL consent is never given to a subject.) A copy of the clinician consent form is faxed to the central RC at Mount Sinai (646-537-8556).

WDM12 – Clinician Demographic Information

The clinician demographic information form is needed so that the name of the clinician can be "auto-populated" in fields throughout the CATI system. The clinician demographic form is completed after the clinician has signed the informed consent form. Completing this form generates the clinician study ID. This form also contains the statement certifying that the appropriate protocol was followed during the consent process.

Specific prompts for questions on this form are as follows:

- Question 6 – This question should be asked as follows:
  "Do you consider yourself to be Hispanic or Latino?"
- Question 7 – Racial Category
  - These categories reflect current NIH categories. Note that a patient may choose more than one race. A patient who self identifies as more than one race is not "other"
  - This question should be asked as follows:
    "What do you consider to be your race?" If the patient does not use one of the racial categories, you may read the list of categories to him/her.
- Question 8 – this question relates to whether the clinician is actually currently (at the time enrolled) certified by ABIM in heart failure and transplant cardiology
- Question 10 – this is the number of patients in the physician's own personal panel of patients, not the total number in the outpatient practice. It should be the number of patients the clinician considers for whom they have primary responsibility. Physicians should not include the patients of NPs/PAs unless they actively manage those patients on an ongoing basis
- Question 11 – this is the subset of the patients in question 10- who have heart failure.
- Question 12 – this is the subset of patients in question 11 who have an ICD
- Question 13 - this does not necessarily mean that the clinician has completed a fellowship – but could be some other form of course or workshop. (e.g. Education on Palliative and End-of-Life Care – EPEC – would be considered specialized training). The interpretation of this question is left open to the clinician.
- Question 14 – like 13, this question is left to the interpretation of the clinician.

WDM96 – Clinician Contact Form

The emergency contact information is needed in case a patient or caregiver at some point in the study endorses suicidal ideation. It may be the clinician's cell

phone, answering service, or pager. Assure the physician it will only be used in the case of suicidal ideation of a participant.

WDM97 – Pretest Survey
The pretest survey is really a baseline assessment of self-competence and comfort with skills. It is administered to all clinicians at the time of study entry.

WDM91 – Clinician Enrollment Failure
Clinician enrollment failure should be relatively rare. As such, no data collection system will exist (i.e. these data are not entered in the EDC). Instead retain a copy of form WDM91 and also fax a copy to the PM. The site investigator and principal investigator will need to be informed, as this may result in an issue of the study not being able to enroll enough patients.

III. Data Collection

Data collection occurs both locally and centrally. Baseline data collection for patients and caregivers is performed by the local RC with all follow-up data collection for patients and caregivers performed by the central RC. Baseline patient chart MRA, and inpatient/outpatient chart abstractions are performed by the local RCs. Local data may be collected on paper and then entered into the EDC or CATI systems. If the local RC is performing phone interviews then he/she should perform these using the CATI system whenever possible, as the CATI system has automatic skips and will reduce errors in data entry. Centrally collected data should be collected directly into the CATI.

Note that at the time the study commences, data collection for patients enrolled near the beginning of the study is scheduled to continue until the end of the study (i.e. the study termination date for all patients is the end of the 5 year study). At one year, we will assess the number of patients who have died to evaluate our power for the third aim. At this point we will determine if we will continue to follow patients over the entire course of the project or if the study should have a finite window for any one patient.

Chart of Outcomes

WISDOM – Table of Outcomes (v4)							
Outcome	**Instrument**	**Patient Interview**	**Caregiver Interview**	**Bereaved Caregiver Interview**	**Physician Interview**	**Chart Review**	**ICD Interrogation**
PRIMARY							
Conversations about ICD Deactivation	ICD outcomes	X primary source		X primary source	X secondary source	X secondary source	
ICD deactivation	ICD outcomes	X secondary source		X secondary source		X primary source	
Caregiver Anxiety, Depression	HADS/ SCID		X	X			
Caregiver PTSD, PGD	SCID, Prigerson		X	X			
SECONDARY							
Patient Physical/Psychological Symptoms	MSAS	X					
Healthcare utilization (admissions – all cause and HF, ED use, clinic visits)		X	X	X		X	
Patient/Caregiver desire for prognosis discussion	LEAP	X	X				
Use of End of Life Care (e.g. ICU, ventilator, hospice)				X		X	
Place of death	Teno tool			X			
Shocks received at end of life	ICD outcomes			primary source		secondary source	primary source
Quality of care/caregiver satisfaction after death	Teno new tool			X			
Correlation between patient and caregiver responses to physical and psychological symptoms		X	X	X			
Costs	No –make sure consents mention that we will also review charts now or after study terminates						

Schedule of Instruments (Based on Timeline v13)

PATIENT			Baseline	3 months	6 months	9 months	12 months/ annually[1]	Q 3 months after 1 year	After Hospitalization[2]		Added after 1st, 3rd Reminder[3]		Added at 3 & 9 mths
									Intervention and Control		*Intervention Only*		*Control Only*
	Assessment Window→		14 d after enroll	+/- 7 days	+/- 7 days	+/- 7 days	+/- 7 days	+/- 7 days	+/- 2 weeks after discharge		+/- 7 days		+/- 7 days
	TOOL ⬇												
Symptoms	MSAS-P		X	X	X	X	X	X	X				
Cognitive Status	Callahan 6 item screen		X				X		X				
Patient Depression / Anxiety	HADS-P		X	X	X	X	X	X	X				
	SCID-D		X	X	X	X	X	X	X				
	SCID-A												
Patient QOL	KCCQ (+1 McGill Question)		X	X	X	X	X	X	X				
Function	Katz ADL-P		X	X	X	X	X	X	X				
Recent Utilization	Utilization-P			X	X	X	X	X	X				
Current Clinician	Current Clinician		X		X		X	Q6					
ICD Shocks	ICD Shocks – Baseline – P		X										
	ICD shocks-P			X	X	X	X	X	X				
Deactivation Discussion	ICD Outcomes – Baseline - P		X										
	ICD Outcomes-P								X		X		X
Desire for Prognosis	LEAP-2-P		X		X		X						
Perception of	LEAP-1-P		X				X		X				

Prognosis													
Advance Care Planning	Advance Care Planning		X		X		X		X		X		x
Human Connectedness Scale	Human Connectedness		X				X						
Comorbidity	Katz comorbidity		X				X						
Demographics[4]	Demo-P		X										
Religiosity	Religiosity-P		X		X		X						
Hsptl Religion visit	Hsptl religion-P								X				
Finance	Two Finance Questions		X										

[1] For patients who live >1 years, they continue to get assessments every 3 months. The "annual" questions are then asked every 12 months.
[2] Hospitalization (any cause) triggers an assessment within 2 weeks after discharge. If this falls into (or within 2 weeks) of a regularly scheduled assessment then addition assessment not needed.
[3] The first and third reminders trigger additional questions at the next assessment, not additional assessments. . This similarly occurs for control patients.
[4.] Patient Demographics collected in EDC, not CATI

CAREGIVER			**Baseline**	**3 month**	**6 month**	**9 month**	**12 months/ annually**	**Q 3 months**	**After Hospitalization** *Intervention and Control*		**Added after 1st, 3rd Reminder** *Intervention Only*		**Added @ 3, 9 months** *Control Only*		**4 wks post death**	**6 mos post death**
	Assessment Window→		14 d after enroll	+/- 7 days	+/- 7 days				+/- 2 weeks after discharge							
	TOOL															
Patient level of alertness	Teno Alertness		X	X	X	X	X	X	x							
Caregiver Depression/ Anxiety	HADS – C		X	X	X	X	X	X	x						x	x
	SCID-D		X	X	X	X	X	X	x						x	x
	SCID-A															
Caregiver health, QOL	Caregiver Health Single question, McGill		X		X		X	Q 6 months							X	X
Caregiver Burden	Caregiver reaction assessment		X		X		X	Q 6 months								
Patient Physical Function	Katz ADL-C		X	X	X	X	X	X	x							
Recent Utilization	Utilization-C			X	X	X	X	X	X							
ICD shocks	ICD Shocks – Baseline C		X													
	ICD Shocks-C								X		X		X		X	
ICD Deactivation Discussion	ICD Outcomes – Baseline – C		X													
	ICD Outcomes-								X		X		X		X	

	C															
Desire for Patient's Prognosis	LEAP – 2 – C		X		X		X									
Caregiver perception of prognosis	LEAP – 1 – C		x				x		X							
Demographics[1]	Demo-C		x													
Caregiver PTSD	SCID-PTSD														x	X
Complicated Grief	Prigerson															x
Quality of EOL Care	Satisfaction EOL Care														X	
Religiosity	Religiosity-C		X		X		X									
Religion visit in hospital	Hsptl religion-C								X							
Finance	Two Finance Questions		X													
Religion Bereaved	Bereaved Religion														X	
Bereavement Closing	Bereavement Closing														X	X

MEDICAL RECORD REVIEW		**Baseline**	**Every Hospitalization**	**Every outpatient visit**
Assessment Window			Within 2 weeks after d/c	When note completed (site dependent)
Seattle Heart Failure Score		X		
Indication for ICD (1 vs. 2)		X		
Type of Device		X		
Ejection Fraction		X	X	X
Etiology of Heart Failure		X		
Date (month/year) of implant		X		
Comorbidity		X		
Insurance		X		
Patient received shock since last interview (as per notes)		X	X	X
DNR Status		X	X	
Living Will/HCP		X	X	
Hospitalized since last interview[1]				X
Indication for hospitalization/outpatient visit			X	X
Discussion about device deactivation			X	X
Device deactivated			X	X
Pall Care Consult			X	X
Other documentation about goals / Family meetings			X	X
CCU / MICU / other ICU use			X	
Inotropes in hospital			X	
Sent home on inotropes			X	
Outpatient use of inotropes				X
Mention of hospice in medical record			X	X
Medical complications during hospitalization			X	
Hospital discharge status/destination/discharge services			X	

Instruments

This portion of the MOP provides instructions on each element of the data collection forms. The data collection forms should all be read verbatim to assure consistency across sites in terms of administration. There are prompts both to introduce the instruments as well as to tell the interviewer when to skip to the next section or instrument. The instrument names are there only so the interviewer will know that he/she is moving to the next instrument; they should not be read to subjects.

Portions of each of the instruments are covered below. Not every portion of the tools is discussed below, as many are easy to administer. Please direct any question to either the site-PI, the PM at Mount Sinai, or the study PI.

DATES ARE OF CRITICAL IMPORTANCE! THE ENTIRE TELEPHONE DATA COLLECTION SYSTEM IS TRIGGERED BY THE DATES ENTERED INTO THE EDC. In addition, given that there are multiple data collections for each subject, the date is a key factor in the analysis. Missing data is always a problem, but missing or inaccurate dates for this study will create multiple problems. In many cases the dates are auto-populated in the EDC, but the form still needs to be created/begun on the appropriate date.

WDM51 - Patient Baseline and Follow-Up

The following elements discuss the WDM51

Memorial Symptom Assessment Scale

- It is often useful for the interviewee if the portion of the stem "in the past week" is repeated. For example, "In the past week did you have dry mouth?" or "And in the past 7 days, how much did difficulty concentrating bother you – not at all, a little bit…"

Hospital Anxiety and Depression Scale

- The responses to the question stems vary for each question, so the responses will need to be read for every stem. For example "I feel tense or wound up" – does that describe your feelings most of the time, a lot of the time, from time to time or occasionally or not at all?"

General notes on the SCID

The Structured Clinical Interview for DSM Axis I Disorders (SCID-I)[9-11] is a semi-structured interview for making diagnoses of the major DSM-IV Axis I diagnoses (e.g. major depression, generalized anxiety disorder). (Note: much of the material in this section is taken verbatim from the SCID.[11])

The SCID always has three columns. The first column is the questions the interviewer is supposed to ask. The SCID is always read verbatim, except for the phrases in parentheses. Questions in parentheses are to be asked when necessary to clarify responses. This does not imply that the information the

question is designed to elicit is any less critical. Those phrases in parenthesis are additional prompts that can be used to clarify whether the specified condition is present or absent.

The second column is the clinical criteria that must be met for that row; that is – the diagnostic criteria to which the interview questions refer. The questions in column one are used to determine if the criteria in column two are present or absent. The material in the second column is for the interviewer, but it is never read to the subject.

The third column is the interviewer's interpretation of the subject's response to the questions. Ratings are of Criterion Items, NOT of answers to questions. Although specific structured questions are provided to help elicit diagnostic information, it is important to keep in mind the fact that the ratings on the SCID are of the diagnostic criteria, and not necessarily the answers to the questions. Although the majority of the SCID questions can be answered by a simple YES or NO, more often than not an unelaborated YES answer is not enough information to determine whether a criterion is met.

Ratings are as follows:

1 = Absent or False

Absent: the symptom described in the criterion is clearly absent (e.g., no significant weight loss or weight gain or decrease or increase in appetite).

False: the criterion statement is clearly false

2 = Subthreshold

The threshold for the criterion is almost, but not quite, met (e.g., subject has been depressed for only 10 days rather than the required two week minimum; subject reports loss of interest in only some activities, but not the required "almost all activities")

3 = Threshold or True

Threshold: the threshold for the criterion is just met (e.g., subject reports being depressed for two weeks) or more than met (e.g., subject reports being depressed for several months)

True: the criterion statement is true

Don't know and refused have been added for these interviews. Don't know is used only when the subject states they don't know or can't answer a particular question – it is different than subthreshold (which would be when the interviewer doesn't know if the criteria are met). Refused is used when a subject does not want to answer a particular question or set of questions.

Additional notes for the SCID:

⇒ **DO** stick to the initial questions, as they are written, except for necessary minor modifications to take into account what the subject has already said, or to request elaboration or clarification.

⇒ **DON'T** make up your own initial questions because you think you have a better way of getting at the same information. Your minor improvement may have a major unwanted effect on the meaning of the question. A lot of care has gone into the exact phrasing of each question and they work in nearly all cases.

⇒ **DO** ask additional clarifying questions in order to elicit details in the subject's own words, such as "Can you tell me about that?" or "Do you mean that....?"

⇒ **DON'T** use the interview as a checklist or true/false test.

⇒ **DO** use your judgment about a symptom, taking into account all of the information available to you, and confronting the subject (gently, of course) about responses that are at odds with other information.

⇒ **DON'T** necessarily accept a subject's response if it contradicts other information or you have reason to believe it is not valid.

⇒ **DO** make sure that the subject understands what you are asking about. It may be necessary to repeat or rephrase questions or ask subjects if they understand you. In some cases it may be valuable to describe the entire syndrome you are asking about.

⇒ **DO** pay attention to double negatives, especially in the exclusion criteria (i.e., is NOT better accounted for by Bereavement) means that a rating of 1 is made if it is better accounted for by Bereavement, and a 3 if it is NOT.

<u>SCID for Depression</u>
If the subject does not have depressed mood or has not lost interest or pleasure in things he/she normally enjoyed then the patient fails the depression screen. The remainder of the SCID for depression is skipped.

Note – if the subject completes the entire SCID, there is a question relating to suicidal ideation. If a subject ever endorses that he/she <u>currently</u> has suicidal ideation, ask if the patient currently has a plan to hurt him/her self. (This question is not part of the SCID.) If the patient endorses current feelings of harm, follow the suicidality flow and complete the suicidality Chain of Events (WDM 95). If the site investigator can't be reached, notify the project manager at Mount Sinai or Dr. Goldstein at 917-312-6745 immediately. This plan is further elaborated in the Serious Adverse Events section of the MOP.

<u>SCID for Anxiety</u>
The first question is the SCID screen for anxiety. If the subject hasn't been anxious or nervous for the past 10 months, the entire SCID for anxiety is skipped.

Callahan 6-Item Screen for Cognitive Status
The Callahan 6 item screen is completed and scored by the interviewer.

Kansas City Cardiomyopathy Questionnaire (KCCQ)
The KCCQ screens for quality of life related to the patient's heart failure.

Activities of Daily Living
The questions for the Katz[12] relate to whether the patient currently has problems with performing these activities. The time frame is thus in the last.

Recent Utilization
A subject who is hospitalized should be queried as to what the cause of the hospitalization was. There is a space to write comments on the form, although these comments will not be entered in the CATI. At the end of the conversation, determine if the hospitalization was related to worsening of the patient's heart failure or an ICD shock. These two categories are not mutually exclusive.

Current Clinician
The current clinician question is to determine the heart failure clinician who the patient considers to be most in charge of his/her heart failure care. It should be the person the patient considers to be his/her primary heart failure clinician. The names in the drop down menu are taken from the clinician contact information form that is completed when clinicians are enrolled. The person named may change through the course of the study.

ICD Shocks
The baseline questions (ICD Shocks Baseline) differ from the follow-up questions. Ask only the baseline question at the time of enrollment. If you are conducting the baseline enrolment, the ICD-Shocks section should be skipped. (Note: if you are performing this using the paper version, when you enter this in the CATI the CATI will automatically skip the ICD-Shocks section.

ICD Outcomes Instrument
Like the ICD shocks tool, the ICD Outcomes Instrument asked at baseline is different than that asked at later sessions.

Advance Care Planning
The Advance Care Planning Sections should be asked even if the interviewer already knows the answers to some of the questions (e.g. if the interviewer has already performed the baseline patient chart abstraction).

LEAP
The LEAP questions are adapted from Dr. Terri Fried's LEAP (Longitudinal Evaluation and Assessment of Preferences) study.[13-14] The skip pattern can be confusing when done on paper, so the interviewer needs to follow the prompts carefully. Both portions of the LEAP are administered at baseline so the distinction between LEAP-1 and LEAP-2 is ignored at baseline (it relates to follow up interviews only.)

Human Connectedness Scale[15]
The Human Connectedness Scale should be asked in relationship to the same person the patient identifies as his/her "current clinician." (This instrument may be removed later depending on the average length of interviews.)

Patient Comorbidity
The patient comorbidity scale is provided here as a way to make things easier on the interviewer who may be completing the study in person using the paper version of the instrument. The answers to these questions are entered into the EDC and not the CATI.

Religiosity
The religiosity questions are straightforward, however note that the hospital religion visit questions are not asked at the baseline assessment.

WDM52 - Caregiver Baseline and Follow-Up
The caregiver baseline and follow-up form is similar that for the patient, however sometimes the questions relate to the patient (e.g. assessment of patient's activities of daily living) whereas other questions relate to the caregiver (e.g. SCID and HADS all relate to the caregiver). It is important that the interviewer emphasize this during the sessions. (Note that not all elements of the caregiver baseline are discussed here in the MOP because either they are discussed above or no explanation is necessary.)

Caregiver Burden and Satisfaction[16-17]
The caregiver burden and satisfaction scale is unique to the caregiver.

Katz Activities of Daily Living
The scale not only asks the patient's ability to do basic activities for himself/herself but for those activities in which the patient is not independent, it also asks the caregiver if he/she assists the patient.

LEAP
Note that the LEAP questions here relate to the caregivers desire for information about prognosis of the patient. It is primarily for the LEAP questions that it is important that patients and caregivers be interviewed separately.

WDM53 - Bereaved Caregiver Instrument
The Bereaved Caregiver instrument is performed by the central RC and not the local RC.

Satisfaction with End of Life Care[18-19]
The prompts in this instrument are all straightforward, however it should be noted that this portion of the instrument is particularly lengthy. It is only completed at

the first assessment, but the central RC must be sure that the entire instrument is collected.

SCID for PTSD[11]
The SCID for PTSD is completed at both the 4 week and the 6 month interview. The SCID for PTSD assumes that the patient's death is a traumatic event for the caregiver.

Prolonged Grief Disorder[20]
The Prolonged Grief Disorder instrument is asked at only the last interview with the bereaved caregiver.

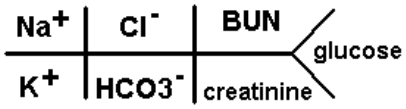
WDM10 - Baseline Patient Chart Abstraction Form
The baseline patient chart abstraction is completed only once for every patient, and should be completed as soon as possible. If you consented the patient while in the outpatient setting, use the most recent data available on file, up to 4 weeks before the date of enrollment (longer time frames acceptable for Seattle Heart Failure Model as noted above). If you consented the patient while in the inpatient setting, the patient data at the time of their hospital admission can be used, but only from the actual day of admission. Do not use data past the first day of admission. For example, if John Smith is admitted from November 1st through November 5th, you may use hospital data from November 1st only. Also if multiple values are present from the admit day – choose the FIRST one available. (Note: This is different than for hospital chart abstraction – where you choose the worst/lowest value.)

Note that the ICD implant note is often a good source of information for many of the questions on this form.

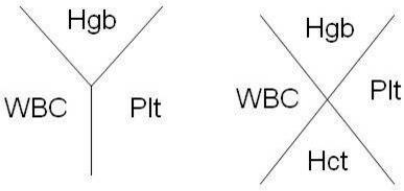
- Question 2- Indication for device
  - Primary Prevention – the device was put in to prevent sudden death
  - Secondary Prevention – patient has a history of life threatening arrhythmia (or inducible VT or VFib)
- Question 4 – Type of device –
  - Single Chamber Device – Device is in only the right ventricle
  - Dual Chamber – Device is in the right atrium and right ventricle
  - Biventricular Device - paces both right and left ventricles; called "biventricular pacing" and the therapy provided by biventricular pacing is called "Cardiac Resynchronization Therapy" (abbreviated as "CRT").
- Question 5- Ejection Fraction – often abbreviated EF – a measure of the amount of blood the left ventricle pumps with each beat of the heart. Use the most recent value in the chart (in relation to date of enrollment)
  - The first option is when there is an actual number – measured as a percent
  - The second options ask for a categorical rating of ejection fraction as noted in the chart.

- Question 5A asks for the EF source
- Question 6- Lab Values and other data – use the most recent values, but do not use data more than 4 weeks prior to the date of study enrollment.
    - Height and weight may be noted in the nurses notes. Height should be recorded in feet and inches, weight in kilograms (weight in lbs / 2.2 = weight in kgs)

    - Some helpful hints for abstracting labs:
        - Sodium



    - Hemoglobin = Hgb



    - Total Bilirubin – may be abbreviated t.bili or tbil
    - BMI – in some cases the chart will not record the height and weight as well the BMI. Record this value in addition to the height and weight. Do not manually calculate the BMI.
    - Question 7, 8, 9 – these are the data used for the SHF model. These should be entered from the screening tool (Note: this is different than other data on the baseline abstraction – which are taken as the most recent data. This also means that the EF recorded in Question 9 may be different from that in question 5. <u>This is the ONLY time the actual enrollment criteria are entered in the system so it is important that these are those at time of eligibility screen!)</u>
- Question 10 -11 – record this from the screening tool – even if this is different than what is currently the case for the patient in the last 12 months. <u>This is the ONLY time the actual enrollment criteria are entered in the system so it is important that these are those at time of eligibility screen!</u>
    - The answer to the “surprise question” is also indicated in this section. Remember that “No” means the physician wouldn’t be surprised if the patient died (a double negative – the clinician might expect the patient would die).
- Questions 12-17 – These can often be taken from the list of medical conditions.
    - Question 14 – Valve replacements are often abbreviated by the first letter of the valve and then VR (e.g. aortic valve replacement = AVR; mitral valve replacement = MVR)

    - Because only one type of valve replacement may be selected, the order of replacements is: aortic>mitral>pulmonic>tricuspid.
- Question 18– Insurance Status
    - Managed care plan is used when the following letters are listed after the insurance name. This may include HMO, PPO, PPS, POS.
    - Uninsured may be indicated differently at each institution. "None listed" may be different than "Uninsured." Check local customs.

WDM09 - Hospital Medical Record Abstraction Form

The hospital medical record abstraction does not need to be completed until 2 weeks after the patient is discharged, but it must be started (i.e. date of admission entered) as soon as possible after admission (preferably the same day). The reason for this is because it will inform the central RC that the patient is in the hospital in case the patient can't be contacted for a routine follow-up. The date of discharge must be entered immediately upon discharge, as it triggers the CATI follow up in two weeks.

***NOTE: We only abstract Heart Failure related hospitalizations and VAD related hospitalizations. Heart Failure related hospitalizations include hospitalizations for worsening cardiac function and may include hospitalizations for shortness of breath, worsening edema, or worsening renal failure. It is important to read the hospitalization notes and discharge summary carefully to determine if a hospitalization is in fact HF or VAD related. Hospitalizations for which reason for admission is unclear should be reviewed with the Site Investigator and subsequently the Project Manager and Principal Investigator if a determination is challenging.

SECTION 1- ADMISSION DETAILS

- Questions 1 – Date of Admission – should be entered as quickly as possible so the form is generated
- Question 2 – Date of Discharge – entering this date triggers the 2 week follow up and as such it must be entered THE SAME DAY OF DISCHARGE. The date of discharge can be entered even if the remainder of the data collection form is not completed.
- Question 4 – Admitting location
    - CCU – Coronary Care Unit
    - MICU – Medical Intensive Care Unit
    - SICU – Surgical Intensive Care Unit
- Question 5 – Insurance – see baseline data collection form
- Questions 6 and 7 – DRGs for admission are taken from the final coded diagnosis for the admission (this may be a separate system depending on the institution)
- Question 8 – Reason for Hospitalization - These data can be abstracted from the admitting note (often the first few notes in the chart), but

should not be taken from the Emergency Room notes. This is not a list of every problem that occurred in the hospital, but the main reason the patient came to the hospital. For example, a patient who comes to the hospital with a gastrointestinal bleed, who gets too much fluid who then goes into heart failure is listed as coming to the hospital only for the GI bleed, not for the heart failure.

SECTION 2-COURSE OF HOSPITALIZATION

- Question 9 – The lab values abstracted should be the earliest ones from the admission. These may be taken from the Emergency Room notes or the admitting notes. These should be the values that the providers first "saw" when the patient presented or was admitted – the values that related to the indications for the admission. For example, if the Hemoglobin in the ER was 6.8, the patient got 3 units of blood in the ER and the repeat hemoglobin when the patient came to the ICU was 9.8, the value to record is 6.8. As of the baseline abstraction, BMI is not calculated but abstracted only if computed in the hospital. Labs should be those drawn in the hospital. (e.g. If the patient was "sent to ED from Clinic for Cr of 4 in the office and it is 3.5 when the patient gets to the ED, the value from the ED is recorded.)
- Question 10 – Calculate the total number of days the patient was in any and all intensive care units.
- Question 12 – Inotropes
    - These medications improve the contractility of the heart (make it pump stronger)
    - Dobutamine (Dobutrex), Milrinone (Primacor) are medications in this class.
    - The dose of these medications given does not need to be recorded – only the number of days the patient was on them. Any part of a day should be recorded as a day (e.g. half a day on milrinone is recorded as 1).
- Question 13 asks if the patient was discharged on inotropes. This may be a different answer then question 12.
- Question 14 – Vasopressors – these medications make the blood vessels contract to improve the patient's blood pressure
    - May include norepinephrine (Levophed), phenylephrine, epinephrine, dopamine, vasopressin (Pitressin)
    - Note the similarities between the names of the medications doBUTAMINE and doPAMINE. These are different classes of medications.
- Question 16 – Renal Replacement Therapy – treatments used to augment or replace the function of the kidneys – includes dialysis, hemodialysis, peritoneal dialysis, CVVH (continuous venous-venous hemofiltration), continuous hemofiltration, SLED (sustained low-efficiency dialysis), CHF solutions, ultrafiltration. One place to look for this is in the notes from the renal service – who may abbreviate it RRT (renal replacement therapy).

The mode of dialysis does not need to be recorded. As with other medications, there are no "partial" days. Intermittent dialysis (e.g. hemodialysis Monday – Wednesday – Friday) – count each day separately (M-W-Fr = 3 treatments, not a week of dialysis). Continuous dialysis procedures (e.g. CVVH) – each part of a day constitutes a separate day (CVVH for 3 days and 5 hours on the 4th day is 4 days of dialysis).

- Question 18 – Hospice consultation is a separate note from a hospice worker, not a social work note or palliative care note stating that the patient is to be enrolled in hospice. A visiting nurse referral form that states the patient is to be enrolled in hospice should be considered a hospice consultation, however.
- Question 21 – Echocardiogram. This is asking if the patient received a NEW echocardiogram during the hospitalization. If the Ejection Fraction is simply repeated from past studies, then this question is answered "no."
- Question 26 – When the ICD is interrogated in the hospital, a report is often placed in the chart. Photocopy this report, assuring that all PHI is removed and/or illegible. The subject's ID is then written on the report. These should be stored locally until the end of the study (they should be notated in a way so it is clear that they are not the after death ICD interrogation report.)
- Question 27 – Review the chart for the words: depression, anxiety, delirium. Also note if there is any mention of a confused state (regardless of cause) that could also be coded as delirium. There does not have to be formal testing (e.g. mini-mental, confusion scales) for these to be noted. If there are psychiatry consults, note them as "yes" only if specifically addressed by the psychiatric consult. (For example, a psychiatry consult called for capacity to make a medical decision should not be noted as treatment for depression unless the psychiatrist specifically mentions depression in the note or recommends treatments.)
- Question 28 – review the notes for the complications of pneumonia, sepsis, or urinary tract infection. Pneumonia is defined as X-ray evidence of pneumonia or treatment of presumed pneumonia with antibiotics based on signs and symptoms. "Sepsis" is different than shock caused by heart failure. It is characterized by two or more of the following conditions occurring simultaneously, in the setting of infection:

  temp>38 or <36; heart rate>90; respiratory rate>20 or $PaCO_2$<32; WBC>12,000 cells/mm^3, <4000 cells/mm^3, or >10% immature band forms. (see reference [21])

  Patients treated for urinary tract infection should have culture confirmation. Only record complications related to the hospitalization. For example, a patient admitted with pneumonia who develops heart failure from it is not a

hospital complication. A patient intubated for heart failure who later develops a urinary tract infection or pneumonia on the ventilator should be noted as a hospital complication.

SECTION 3 – GOALS OF CARE CONVERSATIONS

- Question 29 – Review the chart for mention of a family meeting. While this does not have to be in person, it should be documented as a meeting in the notes. For example “met with wife and son” would be a family meeting but a single line noting “told wife patient is gravely ill” is not a family meeting. If the patient is unconscious the entire hospitalization and there is no family – then note this in question 28. Note that a “family meeting” is a generic term – it may sometimes be a meeting with the patient alone.
- Question 30 – This question related to whether specific treatments were mentioned in the family meeting as opposed to question 29 which asks which general concepts were covered in the meeting.
    - Remember that question 30 – a discussion about “Deactivation of ICD” - is the primary outcome of the study.
- Question 32 – Changes to Defibrillator for Palliative/End-of-Life Care – these are changes related to a change in the overall plan of care – not changes to the defibrillator to adjusting settings. Remember that question 32 is the secondary outcome for the study.

SECTION 4 – DISCHARGE SECTION

- Question 32 – Disposition at Discharge
    - Patients discharged home need to have the services section completed as noted. This is often best taken from the social work or discharge planner notes
    - Note that if a patient dies, entering it on this form does not trigger the telephone system. A separate mortality (WDM05) form must be completed for all patient deaths. Mortality forms should be started as soon as the RC learns of the death, even if the remainder of the hospitalization form or the death form is not completed.
    - Interval from time of ICD shock to death – complete only if documentation of a shock during the admission. If the patient was admitted for a shock outside of the hospital, do not record this here. If the patient is shocked more than once in the hospital, compute this from the last shock that is recorded.
    - Question 33 – Inotropes at discharge – this is completed for all patients. N/A is only used if the patient died. The medications not being indicated or not in line with goals of care is simply recorded as “no”.

WDM11 - Outpatient Medical Record Abstraction Form
This form should be completed for every outpatient visit AFTER the initial visit when the patient is enrolled. (Do not abstract the visit during which the patient was enrolled/consented.) The outpatient medical record is abstracted within two weeks of the visit.

***NOTE: We only abstract Heart failure/cardiology related outpatient appointments. Specifically, appointments with the physician, nurse practitioner, nurse, fellow, etc who are enrolled as a clinician in the WISDOM trial. If an enrolled patient has an outpatient HF/cardiology appointment with a clinician not enrolled in the study, we do not abstract that outpatient appointment, unless the clinician is consented and enrolled in the study prior to the patient's visit.

- Question 2 – Reason for visit – Routine follow-ups should be noted. Appointments marked "urgent" or noted as "patient called needing to come in" should be marked as problem focused/emergent and noted whether it relates to the ICD shock. For example, an appointment noted as "patient called clinic to come in after ICD shock" is a problem-focused visit related to the ICD; a visit where the patient noted a weight gain and called the office to come in to be seen is an emergent visit not related to an ICD shock.
- Question 6- These labs are those noted during the office visit, or drawn prior to the visit. Labs noted in the chart visit that are more than 4 weeks old are not to be considered. (For example, if the patient had labs drawn the week before in anticipation of the visit – these are included. Labs from two months ago that are noted in the current visit should not be abstracted. Labs drawn during the visit – that would *not* have been available to the practitioner during the visit are not abstracted.)
- Question 7 – Echocardiogram – This question is asking if there is a new echocardiogram or ejection fraction since enrollment. If an EF is recorded and it is the same as that at enrollment (i.e. the same as on the baseline form) then mark this as no. If there is a new ejection fraction since enrollment noted, check the "yes" box and write the EF here.
- Question 10 (Palliative Care) and Question 11 (Hospice) – Note whether there is mention of hospice or palliative care in the chart, and whether the patient has been referred or if the clinician is planning on referring the patient.
- Questions 12 -15 – Instructions for completing the section on goals of care can be found in the section on the hospitalization medical record abstraction.

WDM06 - Termination Form
Note – the termination form is used for all patient and caregiver terminations, *including death*. If the patient died, ALSO complete WDM05– Patient Mortality.

This form may be completed by either the local or the central RC, depending on the circumstances. Communication about a termination should happen between the RCs and the PM (via email) in addition to completion of this form.

Note for the purposes of this study, lost to follow-up means that the subject cannot be contacted for two or more consecutive interviews after and including the 3 month interview.

***NOTE, if a patient is lost to follow-up, we still continue to complete hospitalization and outpatient chart abstractions as this is considered a passive withdrawal and the patient has not proactively indicated that they wish to be removed from the study.

At the time the study begins, there is no study completion date. We will monitor the status of subjects over time and determine if there should be a finite window to the study. All subjects will have WDM06 completed at some time, even if it is at the end of the study.

If a patient withdraws or is loss to follow-up and has a caregiver enrolled in the study, we continue to follow that caregiver until the patient withdraws them, the caregiver withdraws themselves, or the caregiver becomes loss to follow-up. For patients or caregivers who withdraw from the study, it is important to write a brief explanation so the investigators will be able to categorize these dropouts during the analysis phase. In addition, it will allow them to determine if there are patterns of drop-outs as the study progresses. This is also true if a particular clinician determines that a patient should be removed from the study. The narrative section is not required to be completed if the reasons for the early termination are self explanatory (e.g. patient moved away).

Miscellaneous End Points:
Artificial heart implant: Termination is date of implant. Select “Other” and explain. Still abstract hospital admission until implant date.

WDM05 - Patient Mortality Form
This form should be started as soon as it is known a patient has died. This form generates the telephone system to schedule the after-death interviews, so <u>entering the date of death as soon as possible in critically important</u>. Whoever (local vs. central RC) first learns of the patient’s death should begin the mortality form immediately – even if all the information isn’t complete. The central RC will always go back to the mortality form after the first bereavement interview and determine that the date is correct. The actual cause of death is determined at the Site Investigator call. Following the determination of death, the PM will advise the local RC so that the form is updated appropriately.

Death are categorized as follows:
<u>CARDIAC</u>

Arrhythmic or Sudden Death
Progressive Pump Failure
Other Cardiac
VAD related

NON-CARDIAC

Sudden Non-Cardiac (e.g. trauma, pulmonary embolism)
Non-Sudden, non-cardiac (e.g. cancer, dementia)

UNABLE TO DETERMINE

If post-mortem ICD interrogation is accomplished, remember to:

- Remove/make illegible all identifying information from the report
- Add the subject ID to the report
- Maintain the report separate from any pre-mortem reports that are obtained

All deaths will be adjudicated by physicians. In the beginning of the study, all deaths will be adjudicated by Drs. Goldstien, Kalman and all the site investigators. After consensus has been reached on the application of these definitions, all other deaths will be adjudicated by the site investigators, Dr. Goldstein, and Dr. Kalman.

Self-administered Surveys (Patient and Caregiver)
The self-administered survey is an adapted version of the follow-up questionnaires. These are used for participants that are having difficulty being reached by telephone. During the first 14 days of their telephone interview window, the central RC will contact a local RC to investigate when a patient is having a clinic appointment.

- If patient's clinic appointment is within two week (14 days), a Local RC will approach participant in person during clinic appointment.
- If participant decides to take questionnaire home, provide a package (self-administered questionnaire with self-stamped envelope).
- If participant decides to complete interview in person, locate a quiet/private area to complete interview and/or collect completed interview and mail back to Mount Sinai.
- If participant decides to schedule an interview over the telephone. Please schedule a date, time and verify telephone numbers. Contact Central RC with telephone and interview details.
- If patient's clinic appointment is scheduled more than 14 days, a Local RC will contact Central RC about mailing a copy of a self-administered questionnaire to participant's home (verify mailing address).

Please note when approaching a patient and/or caregiver at a clinic appointment to generally follow the brief script.

SCRIPT (approaching with self-administered survey)

Good Morning/Afternoon Mr./Ms. _____.

My name is _____ and I'm working with Doctor/Nurse (name clinician enrolled in WISDOM trial whom you emailed for permission to approach patient) _____. You recently participated in a research study titled 'A Study of Symptoms and Quality of Life in Patients with ICDs and Their Caregivers.' We have been unable to reach you by telephone for your _____ follow-up interview. As a reminder, we contact you every 3 months by telephone to complete the questionnaire.

As an alternative, we are providing you with a self-administered survey to gather some information from you for this time period. For your convenience, you can either complete the questionnaire here while you wait to be seen and hand it back to me or you can complete it at home, returning it to us with the enclosed self-addressed stamped envelope.

Your participation in the study is completely voluntary. If you have any questions about this survey or your participation in this study, I can answer them now or you can contact us toll free at 1-855-395-4837.

Thank you for your time and dedication to this research study.

Windows (Timeframes) for Data Collection

The chart below shows the opening and closing dates for collection of all instruments. These windows or timeframes are important for consistency and to assure that data can be collected accurately for all subjects.

- Remember – DATES ARE CRITICAL FOR THIS STUDY. Never change a date to assure that it is in the time frame for a particular instrument.
- Missing data are worse than data outside of a window. In other words, data a week late is better than no data at all. When an entire form or data point is missed, inform the PM at Mount Sinai.

FORM	NAME	COMPLETION WINDOW	SYSTEM	NOTES
WDM01	Patient Enrollment / Demographics	+ 2 weeks enrollment	EDC	
WDM02	Caregiver Enrollment / Demographics	+ 2 weeks enrollment	EDC	
WDM03	Patient Contact Information	+ 2 weeks enrollment	EDC	
WDM04	Caregiver Contact Information	+ 2 weeks enrollment	EDC	
WDM05	Patient Mortality	Immediate for date; 2 weeks for form completion	EDC	Date of death must be completed immediately upon learning of patient's death to trigger CATI; other data can be completed within 2 weeks; central RC verifies at 1st bereavement f/u
WDM06	Termination form	Immediate for date; 2 weeks for form completion	EDC	
WDM07	Co-Morbidity (Patient Report)	+ 2 weeks enrollment	EDC	
WDM08	Patient Eligibility Confirmation	Immediate	EDC	Generates Study ID
WDM09	Hospital Medical Record Abstraction	Admit and D/C Date – immediate; form completion 2 weeks	EDC	Admit date and discharge dates must be entered in "real time" to trigger events in CATI; remainder of data collection can be completed within 2 weeks of discharge
WDM10	Baseline Patient Medical Abstraction Form	+ 2 weeks enrollment	EDC	
WDM11	Outpatient Medical Record Abstraction	+ 2 weeks of appointment	EDC	

WDM12	Clinician Demographic Information	Immediate	EDC	Generates Study ID; name populates fields on the follow up interviews
WDM13	Caregiver Eligibility Certification	Immediate	EDC	Links caregiver to patient ID
WDM14	Patient/Caregiver Screen Failure	+2 weeks after failure date	EDC	
WDM16	Intervention Clinician Survey Form	+2 weeks after PM informs local RC	EDC	
WDM17	Reminder Tracking Tool	Immediate	EDC	The date the reminder was delivered triggers additional questions in the CATI.
WDM19	VAD/Heart Transplant Screening Tool	Immediate for date status change occurs; 2 weeks for form completion	EDC	
WDM51	Patient Baseline/Follow up Instrument	+ 2 weeks enrollment; +/- 2 weeks f/u	CATI	
WDM52	Caregiver Baseline/Follow Up Instrument	+ 2 weeks enrollment; +/- 2 weeks f/u	CATI	
WDM53	Caregiver Bereavement Tool	4 week - + 2 week; 6 month +/- 2 weeks	CATI	
WDM90	Eligibility Screening Tool	N/A	Local	Data not entered but site keeps a list to match names to IDs (waiver of consent for chart review)
WDM91	Clinician Failure	Immediate	Fax to PM	Data not entered – site will keep a local list of clinician failures so not approached in future
WDM95	Subject Suicidality Chain of Events	Immediate	Contact PM or Dr. Goldstein immediately	See suicidal subject flowchart to determine actions needed
WDM96	Clinician Contact Form	Immediate	Fax to PM	Data not entered but site keeps a list to match names to IDs
WDM97	Clinician Pre-Test	Completed at time of physician enrollment	Fax to PM	Done at all sites
WDM98	Intervention Post-Test	Completed at	Fax to PM	Only done at

		end of intervention training		intervention sites.
	Self-Administered Patient Survey	+/- 2 weeks f/u	Paper based mailed or handed	
	Self-Administered Caregiver Survey	+/- 2 weeks f/u	Paper based mailed or handed	

Reports, Accuracy, and Communication

The PM at Mount Sinai will query the databases on a regular basis to prepare enrollment rates and data completion reports.

Enrollment Reports
Enrollment will be monitored weekly by the PM, and will be discussed on the weekly project calls. Monthly enrollment reports will be sent to the site investigators.

Data Completion Reports
The PM will review the EDC and CATI to assure data are being completed and entered in a timely manner. These monthly reports will also review missing data to look for elements that are repeatedly missing so corrective action can be completed.

Accuracy Checking
For the first two quarters and then annually, the site-investigator at each site will need to verify a subset of patient charts to assure internal consistency in the application of the eligibility criteria. The site investigator will also need to verify abstraction and baseline data collection. This process includes:

- The site investigator will randomly select 5 patients who have been screened (not necessarily enrolled) by the RC to determine if the site-investigator comes to the same eligibility conclusion for the patient
- The site investigator will need to review 3 of the inpatient charts the RC abstracted and 3 of the outpatient charts the RC abstracted to assure that the data have been abstracted correctly.
- The site investigator will need to review 3 of the baseline chart abstract forms the RC has completed.
- The site PI will need to observe the RC perform at least 2 patient and 2 caregiver interviews (either done in person or via phone) to assure that the local RC is administering the baseline data instrument correctly.
- At the intervention sites, the site investigator will assess the fidelity to the intervention. This may include reviewing the mechanism the local RC is using to identify patients when hospitalized, their use of the electronic medical record to create the reminders, etc.

Scheduled Communication
Weekly RC Calls

- The PM, central RC, and the local RCs will communicate weekly to discuss study progress and troubleshoot problems. These calls may also include the RCs debriefing about any particularly troubling cases.

Monthly Site Investigator Calls

- The site investigators will continue to have monthly calls for the course of the study.
- Once enrollment begins, the PI, Co-Investigators and Site PIs will begin quarterly calls to discuss enrollment and review SAEs.

Bi-Annual Investigator and Advisory Calls

- The PI, Co-investigators, and advisory panel will communicate twice yearly to review the study progress and review SAEs.

IV. Intervention Procedures

Overview of the Intervention

The intervention consists of three elements: a training session at each site, a reminder system, and a system of aggregated feedback.

1. Training Session:

Drs. Goldstein and Kalman will travel to the intervention sites to conduct an on-site 90 minutes training session that will consist of the following elements

- a review of the study and its objectives
- a review of the relevant literature on communication in heart failure and needs for improving goal setting
- a discussion of current practices and challenges related to these conversations
- use of video to demonstrate an “ideal” conversation about ICD management in the context of a patient’s goals of care
- discussion of video, slides about elements of ideal conversation
- review of video, with added text highlighting elements of the ideal conversation

Clinicians at the intervention sites who do not attend the training session or are subsequently hired after patient enrollment begins will need to attend the training session as well. This training session will consist of a 1:1 conversation with the principal investigator (via skype) and the site investigator as well as a review of the video.

WDM98– Intervention Post-Test

The intervention post test is given to all clinicians when they complete the intervention session.

2. Reminders

Each inpatient hospitalization or outpatient appointment counts as an encounter. For the first three encounters after the patient is enrolled, the physician/ clinician of record will receive a reminder that the patient meets the study entry criteria and therefore is at a high risk of death within the next year. The reminder prompts the clinician to have a conversation about goals of care and address the implantable defibrillator.

The reminder consists of both an email as well as either a hard-copy notice attached to the patient’s inpatient/outpatient chart or a reminder in the electronic medical record. The email is sent the day before (for an outpatient visit) or as soon as the local RC determines that the patient has been admitted the hospital. The email is sent to the outpatient provider who the patient has identified as being his/her primary heart failure clinician as well as the attending of record for inpatient admissions (assuming that attending of record is a study subject).

Hard-copy reminders are also directed to these individuals. Electronic reminders in the EMR should be programmed/entered so they appear when the designated clinician logs in on the particular day of the encounter (outpatient) or when the clinician opens the EMR of the admitted patient.

ENROLLED VAD/TRANSPLANT CANDIDATES: At intervention sites, we do not begin reminders to clinicians until the patient is no longer a VAD/Heart transplant candidate. In other words, if a patient is initially a VAD/Heart transplant candidate, the RCs at intervention sites should NOT begin clinician reminders until the clinician has advised them that the patient became too ill or is no longer a candidate for these therapies. If the patient receives a heart transplant, that is a study endpoint and no reminder will ever be sent for such subjects. If the patient receives a VAD, that is not a study endpoint. If the VAD was implanted as Destination Therapy (DT) then reminders may begin. If the VAD was implanted as Bridge to Transplant (BTT), we do not begin reminders at intervention sites till there is a change in status.

To summarize: Outpatient – email + reminder for clinician. Inpatient – email to outpatient clinician + inpatient attending; reminder to both (assumes they aren't same person and that the inpatient attending is enrolled in study).

For the intervention flow relating to the reminder, see section 1. Reminders 1 and 3 trigger additional questions on the next regularly scheduled patient interview. (This corresponds with the 3 month and 9 month follow-up interview for control patients).

To assure that clinicians aren't overwhelmed with reminders and that there is adequate time for data collection between reminders, at least one month must elapse between reminders. This avoids a situation where several reminders could be delivered in a very short period of time.

3. Aggregated feedback

Each clinician enrolled in the study will receive aggregated feedback after at least one reminder has been sent relating to at least 3 patients. This will assure anonymity of the aggregated results.

The feedback will be delivered via email, and will allow the clinician to compare his/her results to both those at the local institution as well as across all sites if he or she so chooses.

Reminder Template

The following template should be used for the email reminders to the clinician.

Dear <Clinician>:

We wanted to remind you that <PATIENT> who <has been admitted to the hospital> <will be seeing you tomorrow in the outpatient setting> is enrolled in the WISDOM (Working to Improve diScussions about DefibrillatOr Management) trial. The goal of this trial is to improve communication about the patient's desires for his/her care and to encourage conversations about deactivating the patient's implantable defibrillator.

As per our study entry criteria, the patient has a high likelihood of dying within the next year.

It has previously been shown that patients and their caregivers want communication about the severity of their illness, although this rarely happens. The following acronym may make communication easier for you:

RECIPE for communication:

REview - the patient's understanding about his/her heart disease
Clarify - the patient's desired goals and outcomes for his/her health care
Icd – discuss the role of the ICD in meeting these desired goals/outcomes
Plan- make a treatment plan that aligns treatments to desired goals/outcomes
Empathy – ask the patient how he/she is coping with his/her illness

To review the video demonstrating the use of this communication system, go to <website here>.

For questions about the WISDOM Study, contact <RC Contact Information>.

Reminder Log and Tracking Tool

Each site maintains its own local reminder tracking log. A single spreadsheet should be maintained, and it is has only the column for subject ID and dates for the first three encounters. This allows the local RC to keep track of the number of reminders sent.

To assure fidelity to the intervention, this spreadsheet is encrypted and sent to the project manager at Mount Sinai every month for review.

For every encounter (inpatient or outpatient) the local RC consults the tracking spreadsheet. The first three encounters post enrollment each receive a reminder.

WDM17 – Reminder Tracking Tool

The reminder tracking tool is completed for every reminder (1st, 2nd, and 3rd). (The CATI will only trigger additional questions after the first and third reminders.) Be sure at least one month has elapsed between the previous reminder.

- Question 1- Date of Encounter – this is the date of the outpatient appointment or the date the patient was admitted to the hospital. This may or may not be the same date as the reminder elements are delivered.
- Question 3 – Protocol initiated – this question is asking whether the protocol was initiated or if the entire encounter was missed
- Question 4 – Email sent – always request a deliver confirmation when the email is sent, not a read receipt.
- Question 6 - Check “no” if an auto-reply (clinician away) is received. Check unknown if there was no delivery receipt requested.

WDM16 – Physician Survey after 3rd Reminder. (Intervention Only)
The physician survey after the 3rd reminder is delivered by the local RC to the clinician. It is conducted either via email, over the phone, or in person (whatever method works best for particular clinicians.) It is delivered regardless of whether the patient/caregiver states there was a conversation.

Note that the form is actually only one “best answer” question.

Note this form contains both the patient ID and the clinician ID. The PM will inform the local RC to which clinician this form should be administered, based on the patient’s assessment of his/her primary heart failure physician.

The data from this form will be reviewed periodically to see if the categories need to be updated based on “other” responses which clinicians provide.

Reminder Protocol

Outpatient:

The protocol is followed for every outpatient heart failure clinic session, whether it be for physicians, nurse practitioners, or physician assistants. Thus depending on the site, the protocol may be followed anywhere between 1-5 times per week, based on the local outpatient schedule.

TWO DAYS BEFORE APPOINTMENT

1. The local RC checks the schedule for the outpatient heart failure provider and cross-references this with the roster of locally enrolled patients.
2. An email is drafted to each clinician following the reminder template.

ONE DAY BEFORE APPOINTMENT

1. The email is sent to the clinician, assuring a "delivery confirmation" is requested.
2. For electronic medical records, the RC completes the appropriate steps to assure that the electronic reminder will be delivered.
   For hard copy medical records, the hard copy of the reminder template is created.

DAY OF APPOINTMENT

1. For hard copy medical records, the paper version of the reminder is attached to the clinic chart. (For early morning appointments this can be done the afternoon before.
2. At the end of the clinic session, the RC verifies that the patient came to the session. If the patient did not come to the appointment, the entire reminder is voided – do not enter anything into the EDC.
3. The reminder tracking tool must be completed in the EDC within 24 hours of the outpatient appointment.

WITHIN TWO WEEKS AFTER APPOINTMENT

The RA completes the outpatient MRA form.

Inpatient:

1. The local RC checks the list of enrolled patients with the hospital system daily to determine if enrolled patients are admitted to the hospital.
2. Emails:
   a. Email the clinician the patient has identified as his/her primary heart failure clinician.
   b. If the clinician is not the attending of record for the admission, the RC determines who this attending is and also emails that individual (assuming the individual is enrolled in the study).
3. Reminders:
   a. For hard copy reminders, attach the hard copy of the reminder to the front of the patient's chart, using the name of the attending of record AND the clinician the patient has identified.

b. For EMRs, create the pop-up/note template to be seen by the attending of record AND the clinician the patient has identified.

Qualitative Interviews – Year 5

At the end of the project, the PI will travel to all intervention sites to interview the enrolled clinicians to ask their perceptions of the study, whether the intervention worked, and what could have been improved.

V. Forms and Data Collection Instruments

Guide to Forms

The key to the forms is below. Copies of the forms themselves are in the MOP after this page.

Form	Document	Version Number	Date	Type
WDM01	Enrollment/Demographics - Patient	2.1	8/23/2012	EDC
WDM02	Enrollment/Demographics - Caregiver	2.0	8/2/2012	EDC
WDM03	Patient Contact Information Form	2.0	8/2/2012	EDC
WDM04	Caregiver Contact Information Form	2.0	8/2/2012	EDC
WDM05	Patient Mortality Form	3.0	5/28/2013	EDC
WDM06	Subject Termination Form	3.0	1/15/2014	EDC
WDM07	Patient Comorbid Illness Form	2.0	8/2/2012	EDC
WDM08	Patient Eligibility Certification Form	3.0	1/22/2014	EDC
WDM09	Patient Hospital Chart Abstraction Form	2.2	6/14/2013	EDC
WDM10	Patient Baseline Chart Abstraction Form	3.1	1/22/2014	EDC
WDM11	Patient Outpatient Chart Abstraction Form	2.1	8/23/2012	EDC
WDM12	Clinician Demographic Information Form	2.0	8/2/2012	EDC
WDM13	Caregiver Eligibility Certification Form	2.0	8/2/2012	EDC
WDM14	Subject Screen Failure Form	3.0	1/22/2014	EDC
WDM16	Physician Survey Post 3rd Reminder (Intervention Only)	2.0	8/2/2012	EDC
WDM17	Clinician Reminder Tracking for Patient Encounters Tool	2.0	8/2/2012	EDC
WDM19	VAD/Transplant Screening Tool	2.1	9/24/2012	EDC
WDM51	Patient Baseline/Follow up Questionnaire	2.0	8/2/2012	CATI
WDM52	Caregiver Baseline/Follow Up Questionnaire	2.0	8/2/2012	CATI
WDM53	Bereavement Caregiver Questionnaire	2.0	8/2/2012	CATI
WDM90	Eligibility Screening Tool	3.0	1/22/2014	Local

WDM91	Clinician Refusal Form	2.0	8/2/2012	Local
WDM92	Documentation of Informed Consent for Patient Charts	2.0	8/2/2012	Local
WDM93	Patient Interview Guide		8/2/2012	
WDM94	Caregiver Interview Guide		8/2/2012	
WDM95	Subject Suicidality Chain of Events Form	2.0	8/2/2012	Local
WDM96	Clinician Contact Information Form	2.0	8/2/2012	EDC
WDM97	Clinician Pre-test Form	2.0	8/2/2012	Local
WDM98	Clinician Post-test Form	2.0	8/2/2012	Local
MOP	Manual of Procedures	4.0	2/26/2014	
	Instrument Timeline	13	8/30/2012	
	Site Visit Report	1.0		
	WISDOM One-Pager	5.0	1/22/2014	
	Self-Administered Caregiver Survey	1.1	1/22/2014	
	Self-Administered Patient Survey	1.0		

VI. Serious Adverse Events

Patient Suicidality

The patient and caregiver assessments include questions related to depression. One of the questions in the SCID specifically asks about the issue of suicidality as follows:

> Were things so bad that you were thinking a lot about death or that you would be better off dead? What about thinking of hurting yourself?

If the patient states this is true, ask if they currently have a plan to hurt themselves. If the patient states they do, take the following steps:

- If you are with the subject in an inpatient or outpatient setting – immediately inform a member of the patient's heart failure team.
- If you are with the subject but there is no member of the patient's heart failure team immediately available, escort the subject to the hospital emergency room.
- If you are conducting an interview over the phone, explain to the subject the concerning nature of these statements, and encourage the subject to proceed to the nearest emergency room.

Note that this procedure is outlined in the Subject Suicidality Flow.

Some sample language to use when speaking to subjects expressing suicidality:

> "It seems as though you might be depressed. Your health and safety is very important to those of us in the research study. What you've said makes me concerned that you might be thinking about hurting yourself. In these cases, it is important that your safety be our number one priority. I'd like to <take you / have you go> to the nearest emergency room so we can make sure someone can help you with these feelings. What are your thoughts about that? <Pause> If refuses add: OK I understand. But because I'm so concerned about your safety I'm going to have someone else call/come in and see you as well."

Regardless of which action is taken, you must inform the site-investigator and the PM at Mount Sinai immediately. All RCs should have the emergency contact numbers of their site investigator. The RC should have the emergency contact numbers of the clinician subjects as well in case the site investigator wants to speak with the patient's clinician. (That is – the site-investigator may immediately need the number of the patient's heart failure clinician). The PM at Mount Sinai should be emailed immediately and then called the next business day. If the local RC cannot contact anyone local at their site, Dr. Goldstein should be informed (cell phone - 917-312-6745).

Even though the study is not the cause of the patient's suicidality, this is considered a serious adverse event and will be reported to the IRB at the site as well as Mount Sinai.

Inappropriate ICD Deactivation

Inappropriate deactivation of ICDs will be exceedingly rare, as by definition the entry criteria select for people who are candidates for ICD deactivation due to their limited life-expectancy. Likewise the purpose of the study is to encourage conversations about deactivation, not to force ICD deactivation. In addition, the physicians caring for these patients are all heart failure clinicians and would be unlikely to inappropriately deactivate portions of a device (e.g. pacer) when not warranted. Thus a truly “inappropriate” deactivation would be a device turned off which was then later turned back on. This would be noted in the medical record of the patient, and is so highly unusual that it would be clearly documented. (Note this is different than a patient who chooses to have the device deactivated and then later changes his/her mind. This is not considered an AE.) If inappropriate deactivation is noted on chart review of inpatient or outpatient charts, it will be reported as a serious adverse event to both the IRB at the site as well as Mount Sinai. If there is difficulty determining if a deactivation is inappropriate, inform the site investigator, who will contact the PI and the case will be adjudicated between the Site Investigator, the PI, and the co-investigators. If needed, the consulting electrophysiologist will review the case as well.

Breech of HIPAA or Patient Confidentiality

Patient privacy and confidentiality is an important research consideration. In the event that patient privacy or confidentiality is breeched, inform the site investigator, the PM and the PI at Mount Sinai. All breeches of confidentiality are reported to the local IRB and the Mount Sinai IRB.

VII. Site Visits

Project staff at Mount Sinai will make three site visits each year, and each site will be visited every other year. (Staff will conduct a “site visit” at Mount Sinai as part of this regular schedule of visits as well.) The elements of the site visit include:

- Date of visit
- Purpose of visit
- Who site visitors met with and total hours on activities
- Adherence to:
    - procedures for enrolling patients, caregivers, and clinicians.
    - data security
    - keeping study protocols updated
    - medical record abstraction
    - reporting procedures for adverse events
    - documenting ineligible patients/screen failures
    - maintaining appropriate screening logs and watch lists
    - post-mortem ICD interrogation protocol
    - intervention procedures (as applicable)

The original copy of the site report visit is kept on file at Mount Sinai; a copy is provided to the site investigator at each site.

The site visit tool begins on the next page.

VIII. Contact List

IX. APPENDIX

Presentations

Presentations from the training sessions begin on the next page.

Grant Body

The grant application begins on the next page.

X. References

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