FORM NO. SEN001

Study ID:

Date source form completed (mm/dd/yyyy): ____/____/_____

Screening Form

A screening form should be completed for EVERY potential participant that is: ≥ 18 and < 80 years of age (inclusion criterion #1) AND a cancer survivor with diagnosis of AIC (inclusion criterion #2).

Date screened (mm/dd/yyyy): ____/____/_____

Sex: Male ☐ Female ☐

Age: _____ (years)

Hispanic, Latino or Spanish Origin: Yes ☐ No ☐

Race (check all that apply):

- ☐ White
- ☐ Black or African American
- ☐ Asian
- ☐ Native Hawaiian or Other Pacific Islander
- ☐ American Indian or Alaska Native
- ☐ Other

How did the subject first find out about this study? *Please choose the closest answer.*

- ☐ Cardiologist or other physician
- ☐ Research nurse or other non-physician medical personnel
- ☐ Clinicaltrials.gov website
- ☐ Internet (not including clinicaltrials.gov)
- ☐ Facebook or Twitter
- ☐ Newspaper/magazine
- ☐ Hospital flyer or other print advertisement
- ☐ Radio/TV
- ☐ Referred by a friend or other non-medical person
- ☐ Other (please specify):_____
- ☐ No response

Inclusion Criteria

1	Is the subject ≥ 18 and < 80 years of age?	☐ Y	☐ N	
2	Is the subject a cancer survivor with diagnosis of AIC?	☐ Y	☐ N	
3	Does the subject have an LVEF ≤ 45% by cMRI?	☐ Y	☐ N	☐ Not Available
4	Is the subject in NYHA class II or III?	☐ Y	☐ N	☐ Not Available

FORM NO. SEN001				
Study ID:				
Date source form completed (mm/dd/yyyy): ____/____/_____				
Screening Form				
5	Has the subject received the initial diagnosis of AIC at least six months earlier and be on stable, optimally-tolerated therapy with beta-blockers, ACE inhibitors/ARBs, and/or aldosterone antagonists for 3 months, unless contraindicated?	☐ Y	☐ N	☐ Not Available
6	Does the subject have a period of at least two years of clinical cancer-free state* and low likelihood of recurrence (a five-year risk of recurrence estimated at 30% or less), as determined by an oncologist, based on tumor type, response to therapy, and negative metastatic work-up at the time of diagnosis? **exceptions to this are carcinoma in situ or fully resected basal and squamous cell cancer of the skin*	☐ Y	☐ N	☐ Not Available
7	Is the subject a candidate for cardiac catheterization?	☐ Y	☐ N	☐ Not Available
8	Does the subject agree to participate in this trial *(if subject is not approached, select "Not Available" or leave blank)*? ☐ Declined *(includes if subject does not respond to coordinator outreach)* ☐ Does not want placebo ☐ Does not want cell therapy ☐ Could not decide ☐ Too far / Transportation issues ☐ Family issues or concerns ☐ Unwilling to participate in study procedures and/or follow-up ☐ Too busy / Too much going on ☐ Other reason not listed above (please specify): _____ ***(Do NOT include protocol-related reasons for ineligibility here)***	☐ Y	☐ N	☐ Not Available
Exclusion Criteria	☐ **No evidence in medical record of an exclusion**			
If box above is checked, the rest can be blank, or select 1 or more criteria below for a screen failure.				
1	Does the subject have a life expectancy <12 months?	☐ Y	☐ N	☐ Not Available
2	Does the subject have a CT scan or baseline cardiac MRI showing new tumor or suspicious lymphadenopathy raising concern of malignancy?	☐ Y	☐ N	☐ Not Available
3	Does the subject have presence of obstructive CAD as determined via imaging within 5 years prior to study enrollment provided there have been no symptoms or evidence of CAD since the test (see Section 4.1 for imaging guidance)?	☐ Y	☐ N	☐ Not Available
4	Has the subject had a previous myocardial infarction?	☐ Y	☐ N	☐ Not Available

FORM NO. SEN001				
Study ID:				
Date source form completed (mm/dd/yyyy): ____/____/_____				
Screening Form				
5	Does the subject have a history of radiation therapy AND evidence of constrictive physiology and/or evidence of other patterns of non-ischemic cardiomyopathy on cardiac MRI (e.g., amyloidoisis, sarcoidosis, hemochromatosis, pure radiation-induced cardiomyopathy, etc.) not consistent with AIC being the dominant etiology of heart failure?	☐ Y	☐ N	☐ Not Available
6	Does the subject have severe valvular heart disease including mechanical or bioprosthetic heart valve; or 2) severe valvular (any valve) insufficiency/regurgitation within 12 months of consent?	☐ Y	☐ N	☐ Not Available
7	Does the subject have aortic stenosis with valve area ≤ 1.5cm^2?	☐ Y	☐ N	☐ Not Available
8	Does the subject have a history of LV reduction surgery or cardiomyoplasty?	☐ Y	☐ N	☐ Not Available
9	Does the subject have evidence of cardiogenic shock?	☐ Y	☐ N	☐ Not Available
10	Does the subject have a history of ischemic or hemorrhagic stroke within 90 days of baseline testing?	☐ Y	☐ N	☐ Not Available
11	Does the subject have liver dysfunction during baseline testing, as evidenced by enzymes (e.g., AST, ALT, alkaline phosphatase) greater than 3 times upper limit of normal?	☐ Y	☐ N	☐ Not Available
12	Does the subject have diabetes with poorly controlled blood glucose levels (HbA1c > 8.5%)?	☐ Y	☐ N	☐ Not Available
13	Does the subject have an underlying autoimmune disorder or current immunosuppressive therapy (e.g., chronic corticosteroid, rheumatologic or immune modulating therapy) or likelihood of use of immunosuppressive therapy during participation in the trial *(medications will be considered on a case by case basis)* ?	☐ Y	☐ N	☐ Not Available
14	Does the subject have a baseline eGFR < 35 ml/min/1.73m^2 ?	☐ Y	☐ N	☐ Not Available
15	Does the subject have a contrast allergy that cannot adequately be managed by premedication?	☐ Y	☐ N	☐ Not Available
16	Has the subject received gene or cell-based therapy from any source within the previous 12 months?	☐ Y	☐ N	☐ Not Available

FORM NO. SEN001				
Study ID:				
Date source form completed (mm/dd/yyyy): ____/____/_____				
Screening Form				
17	Does the subject have a hematologic abnormality during baseline testing as evidenced by hemoglobin < 9 g/dl; hematocrit < 30%; absolute neutrophil count < 2,000 or total WBC count more than 2 times upper limit of normal; or platelet values < 100,000/ul?	☐ Y	☐ N	☐ Not Available
18	Does the subject have evidence of active systemic infection at time of study product delivery?	☐ Y	☐ N	☐ Not Available
19	Does the subject have HIV, and/or active HBV or HCV?	☐ Y	☐ N	☐ Not Available
20	Does the subject have coagulopathy (INR > 1.5) not due to a reversible cause (e.g., warfarin and/or Factor Xa inhibitors) (see Section 6.4 re: injection procedure and anticoagulation therapy)? *Note: Subjects who cannot be withdrawn from anticoagulation will be excluded.*	☐ Y	☐ N	☐ Not Available
21	Does the subject have presence of LV thrombus *(see guidance in Section 6.6.3)* ?	☐ Y	☐ N	☐ Not Available
22	Does the subject have presence of a pacemaker and/or ICD generator with any of the following limitations/conditions? **If yes, please check the relevant limitation(s)/condition(s) below (required):** ☐ manufactured before the year 2000 ☐ leads implanted < 6 weeks prior to consent ☐ non-transvenous epicardial, or abandoned leads ☐ subcutaneous ICDs ☐ leadless pacemakers ☐ any other condition that, in the judgement of device-trained staff, would deem an MRI contraindicated?	☐ Y	☐ N	☐ Not Available
23	Is the subject pacemaker-dependent with an ICD? *(Note: pacemaker-dependent candidates without an ICD are not excluded)*	☐ Y	☐ N	☐ Not Available
24	Does the subject have a CRT device implanted < 3 months prior to consent?	☐ Y	☐ N	☐ Not Available
25	Does the subject have other MRI contraindications (e.g. subject body habitus incompatible with MRI)?	☐ Y	☐ N	☐ Not Available
26	Has the subject had an appropriate ICD firing or ATP for ventricular fibrillation or ventricular tachycardia within 30 days of consent?	☐ Y	☐ N	☐ Not Available
27	Has the subject had ventricular tachycardia ≥ 20 consecutive beats without an ICD within 3 months of consent, or symptomatic Mobitz II or higher degree atrioventricular block without a functioning pacemaker within 3 months of consent?	☐ Y	☐ N	☐ Not Available

FORM NO. SEN001				
Study ID:				
Date source form completed (mm/dd/yyyy): ____/____/_____				
Screening Form				
28	Does the subject have a history of drug abuse (illegal "street" drugs except marijuana, or prescription medications not being used appropriately for a pre-existing medical condition) or alcohol abuse (≥ 5 drinks/day for > 3 months), or documented medical, occupational, or legal problems arising from the use of alcohol or drugs within the past 24 months?	☐ Y	☐ N	☐ Not Available
29	Does the subject have cognitive or language barriers that prohibit obtaining informed consent or any study elements (interpreter permitted)?	☐ Y	☐ N	☐ Not Available
30	Is the subject participating (currently or within the previous 30 days) in a cardiac related investigational therapeutic (including stem cell based therapies) or device trial?	☐ Y	☐ N	☐ Not Available
31	Is the subject pregnant or lactating or planning to become pregnant in the next 12 months, or is unwilling to use acceptable forms of birth control during study participation?	☐ Y	☐ N	☐ Not Available/ Not Applicable
32	Is there presence of any other condition that, in the judgment of the Investigator or Sponsor, would impair enrollment, study product administration, or follow-up?	☐ Y	☐ N	☐ Not Available
Comments:				

Entered to eCRF ☐ Initials _____

FORM NO. SEN002

Date source form completed (mm/dd/yyyy): ____/____/_____

Demographics

First Name:

Middle Name:

Last Name:

Has the participant signed the consent form?

Yes ☐ No ☐

If yes, Date of Consent (mm/dd/yyyy):

____/____/_____

If no, please check a reason below:

- ☐ Declined
- ☐ Does not want placebo
- ☐ Does not want cell therapy
- ☐ Could not decide
- ☐ Too far / Transportation issues
- ☐ Family issues or concerns
- ☐ Unwilling to participate in study procedures and/or follow-up
- ☐ Too busy / Too much going on
- ☐ Other (specify): _____

Biorepository Consents signed:

Blood samples	Y ☐	N ☐
Explanted heart	Y ☐	N ☐
Samples for future CV research	Y ☐	N ☐
Samples for genetic CV research	Y ☐	N ☐
Inclusion of de-identified information	Y ☐	N ☐

Date of Birth (mm/dd/yyyy): ____/____/_____

Gender: Male ☐ Female ☐

Hispanic, Latino, or Spanish Origin: Yes ☐ No ☐ No response ☐

Race (check all that apply):

- White ☐
- Black or African American ☐
- Asian ☐
- Native Hawaiian or Other Pacific Islander ☐
- American Indian or Alaska Native ☐
- Other ☐
- No response ☐

Marital Status (choose one):

- Married ☐
- Living with a partner ☐
- Single/never married ☐
- Widowed ☐
- Divorced ☐
- Separated ☐
- No response ☐

Highest Education Level (choose one):	
Unknown	☐
Some schooling (no diploma)	☐
High School Diploma or GED	☐
Some college or Associate's Degree (2 years)	☐
Bachelor's Degree (4 years)	☐
Master's Degree	☐
Doctorate Degree	☐
Professional Degree (MD, DDS, DVM, JD, etc.)	☐
No response	☐

Comments:

Entered to eCRF ☐ Initials _____

FORM NO. SEN003

Acrostic Identifier:

Study ID:

Date source form completed (mm/dd/yyyy): _____/_____/_____

Protocol Deviation/Violation Report

Date of the Event (mm/dd/yyyy): _____/_____/_____ ☐ Event has not yet occurred (exemption request)

Date the site study team had knowledge of the Event (mm/dd/yyyy) : _____/_____/_____

This Event meets the criteria for a protocol deviation/violation because :

☐	1	The event resulted in an accidental or unintentional change to the IRB approved protocol and procedures with or without prior sponsor approval.
☐	2	The event affected the participant's rights, safety, or welfare, or the integrity of the resultant data.

Note: The event must meet at least one of the above criteria to be considered a protocol deviation/violation.

Describe the protocol deviation/violation: ***Reminder: Include visit type if applicable***

Explain why or how the deviation/violation occurred:

Indicate the outcome (PI's assessment of the outcome, comments, or determinations):

Describe what action you have taken to prevent recurrence:

PI Signature_____ Date:_____/_____/_____

RNC Signature_____ Date:_____/_____/_____

Entered to eCRF ☐ Initials _____

CCTRN Exemption/Waiver Documentation (DCC only)

CCTRN Medical Officer or Designee Review :

☐ **Exemption Granted** ☐ **Deviation Acknowledged**

Reportable per site's IRB policies:	☐ Yes-immediate reporting ☐ Yes-continuing review ☐ No-not reportable
IRB documentation received?	☐ Yes ☐ No if Yes, Date Received: _____ If No, explain:

DCC Signature_____ Date:_____/_____/_____

FORM NO. SEN004		
Is this unanticipated problem specific to an individual subject ?		☐ Yes ☐ No
Acrostic Identifier: *(fill in if answer to above is "Yes")*		
Study ID: *(fill in if answer to above is "Yes")*		
Site: *(fill in if answer to above is "No")*		
(Note: If the UP does not apply to an individual subject, the Acrostic Identifier and Study ID remain blank)		
Date source form completed (mm/dd/yyyy): _____/_____/_____		

Unanticipated Problem (UP) Report

Definition of an UP: Any problem or event which in the opinion of the local researcher was unanticipated, serious and at least possibly related to the research procedures.

These should be reported to the IRB within 10 working days.

Date of the Event (mm/dd/yyyy)**:** _____/_____/_____

Date the site study team had knowledge of the Event (mm/dd/yyyy)**:** _____/_____/_____

This Event meets the criteria for an unanticipated problem because:

☐	1	**Unanticipated:** The event is unexpected in terms of nature, severity or frequency given the research procedures described in the protocol, consent, etc. or given the characteristics of the population being studied.
☐	2	**Related:** The event is related or possibly related to participation in the research. There is a reasonable possibility that the incident, experience, event, or outcome may have been caused by the procedures involved in research.
☐	3	**Serious:** The event placed subjects or others at greater risk (including physical, psychological, economic, or social harm) that was previously known or recognized or resulted in harm to the subject or others.

Note: The event must meet all of the above criteria to be considered an unanticipated problem.

Describe the type of event:

☐	Accidental or unintentional change to the IRB-approved protocol that resulted in risk or has the potential to recur.
☐	Publication in the literature, safety monitoring report, or other findings indicating an unexpected change to the risks or potential benefits of the research.
☐	Complaint of a participant that indicates an unanticipated risk or which cannot be resolved by the research staff.
☐	A breach in confidentiality that may involve risk to that individual or others (e.g. compromised/stolen computer).
☐	Incarceration of a member of the research staff.
☐	Any other event that, in the opinion of the PI, constitutes an unanticipated risk.

Description of the unanticipated problem:

Provide a plan to prevent the problem from reoccurring in the future (indicate if protocol or consent modifications are required due to the event):

PI Signature_____ Date:_____/_____/_____

RNC Signature_____ Date_____/_____/_____

Entered to eCRF ☐ Initials _____

FORM NO. SEN005		
Acrostic Identifier:		
Study ID:		
Date source form completed (mm/dd/yyyy): _____/_____/_____		
Treatment Checklist		
If eligible, proposed date for SPI (mm/dd/yyyy): _____/_____/_____		
Screening LVEF (from MRI Core Lab report)		Must be ≤ 45%
The following variables are autopopulated from the previously completed Demographics, Baseline Physical Exam, Baseline Laboratory Tests, Baseline Risk, and Medications Forms:		
Variable	**Value**	**Criteria to Proceed**
Subject age		Must be ≥ 18 and < 80 years old at consent date
NYHA class		Must be class II or III
eGFR		Must be ≥ 35
HbA1C		Must be ≤ 8.5
Hemoglobin		Must be ≥ 9
Hematocrit		Must be ≥ 30
Platelets		Must be ≥ 100 K
INR		Must be ≤ 1.5 or taking anticoagulation therapy
Pregnancy Test		Must be "Negative" if female of childbearing potential or N/A if not of childbearing potential or male
Myocardial infarction		Must be "No"
Aortic Stenosis		Must be “Yes” to valve area > 1.5 cm^2 if Aortic Stenosis or N/A if not aortic stenosis or valvular heart disease not present
Temperature		Must be < 100.4 ºF
If any of the variables above have changed since the Baseline Physical Exam or Baseline Laboratory Tests and a more recent exam or test has been done, please enter the updated value, date, and time of the re-check.		

Variable	**Value**	**Date**	**Time**
NYHA class		____/____/_____	
eGFR		____/____/_____	
HbA1C		____/____/_____	
Hemoglobin		____/____/_____	
Hematocrit		____/____/_____	
Platelets		____/____/_____	
INR		____/____/_____	
Temperature		____/____/_____	

FORM NO. SEN005		
Acrostic Identifier:		
Study ID:		
Date source form completed (mm/dd/yyyy): _____/_____/_____		
Treatment Checklist		
Please answer the following questions:		
1. Since the baseline exam and tests, has there been a change in the subjects' condition that would prohibit continuation in the study? (If yes, please explain in Comments)	Yes ☐	No ☐
2. Is there any other reason you think this subject should not continue in the study? (If yes, please explain in the Comments)	Yes ☐	No ☐
Comments:		
☐ Investigator reviewed Treatment Checklist worksheet Date Investigator reviewed (mm/dd/yyyy): ___/___/_____		

Investigator Signature_____ Date:_____

RNC Signature_____ Date:_____

Entered to eCRF ☐ Initials _____

FORM NO. SEN007	
Acrostic Identifier:	
Study ID:	
Date source form completed (mm/dd/yyyy): _____/_____/_____	
Randomization	
Confirmed date for SPI (mm/dd/yyyy): _____/_____/_____	***Reminder: This form must be submitted ≥ 3 days and ≤ 7 days prior to the scheduled injection procedure***
Comments:	

Entered to eCRF ☐ Initials _____

FORM NO. SEN008	
Date source form completed (mm/dd/yyyy): ____/____/_____	
Stress Echo	
This form only to be entered when a subject has not had imaging to rule-out CAD in the specified timeframe and standard of care imagining is not clinically indicated.	
Date of stress echo (mm/dd/yyyy): ____/____/_____	
Was a stress echo performed and CAD ruled-out? Yes ☐ No ☐	***If CAD is <u>not</u> ruled out, subject is excluded.***
Comments:	

Entered to eCRF ☐ Initials _____

FORM NO. SEN009

Acrostic Identifier:

Study ID:

Date source form completed (mm/dd/yyyy): _____/_____/_____

Minnesota Living With Heart Failure Questionnaire (MLHFQ) - Baseline, Month 6, and Month 12

Visit Type:

Patient did not respond to survey ☐

The following questions ask how much your heart failure (heart condition) affected your life during the past month (4 weeks). After each question, circle the 0, 1, 2, 3, 4 or 5 to show how much your life was affected. If a question does not apply to you, circle the 0 after that question.

Did your heart failure prevent you from living as you wanted during the past month (4 weeks) by -	**No**					**Very Much**
		Very Little				
1. causing swelling in your ankles or legs?	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
2. making you sit or lie down to rest during the day?	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
3. making your walking about or climbing stairs difficult?	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
4. making your working around the house or yard difficult?	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
5. making your going places away from home difficult?	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
6. making your sleeping well at night difficult?	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
7. making your relating to or doing things with your friends or family difficult?	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
8. making your working to earn a living difficult?	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
9. making your recreational pastimes, sports or hobbies difficult?	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
10. making your sexual activities difficult?	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
11. making you eat less of the foods you like?	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
12. making you short of breath?	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

NR = No response

FORM NO. SEN009
Acrostic Identifier:
Study ID:
Date source form completed (mm/dd/yyyy): _____/_____/_____

Minnesota Living With Heart Failure Questionnaire (MLHFQ) - Baseline, Month 6, and Month 12

	No					Very Much
		Very Little				
13. making you tired, fatigued, or low on energy?	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
14. making you stay in a hospital?	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
15. costing you money for medical care?	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
16. giving you side effects from treatments?	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
17. making you feel you are a burden to your family or friends?	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
18. making you feel a loss of self-control in your life?	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
19. making you worry?	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
20. making it difficult for you to concentrate or remember things?	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
21. making you feel depressed?	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Comments:

Entered to eCRF ☐ Initials _____

NR = No response

FORM NO. SEN011	
Acrostic Identifier:	
Study ID:	
Date source form completed (mm/dd/yyyy): _____/_____/_____	

Baseline Risk

Non-CV History - ***Responses should reflect past medical history of ever having any of the following***

Diabetes	No ☐	Yes ☐		
Hypertension	No ☐	Yes ☐		
Hyperlipidemia	No ☐	Yes ☐		
Hypercholesterolemia	No ☐	Yes ☐		
Hypertriglyceridemia	No ☐	Yes ☐		
BMI	Enter value: _____			
Smoking	Never ☐	Previous ☐	Current ☐	
	If Previous/Current, years smoked: ___	packs/day: _____		
Thyroid disease	No ☐	Yes ☐		
	If yes, specify: Hyper ☐	Hypo ☐	Unknown ☐	
Liver disease	No ☐	Yes ☐		
Autoimmune disorder	No ☐	Yes ☐		
	If yes, specify type: _____			
	If yes, specify therapy: _____			

CV History - ***Responses should reflect past medical history of ever having any of the following***

Myocardial infarction	No ☐	Yes ☐		
Atrial fibrillation	No ☐	Yes ☐		
	If yes, date of onset: _____			
Ventricular arrhythmia	No ☐	Yes ☐		
	If yes, date of late episode: _____			
Hemorrhagic stroke	No ☐	Yes ☐		
	If yes, specify: Deficit ☐	Completely resolved ☐	Unknown ☐	
	If yes, date of most recent: _____			
Ischemic stroke	No ☐	Yes ☐		
	If yes, specify: Deficit ☐	Completely resolved ☐	Unknown ☐	
	If yes, date of most recent: _____			
TIAs	No ☐	Yes ☐		
Angina	No ☐	Stable ☐	Unstable ☐	
	If stable/unstable, date of most recent: _____			
CAD	No ☐	Yes ☐		

FORM NO. SEN011	
Acrostic Identifier:	
Study ID:	

Date source form completed (mm/dd/yyyy): _____/_____/_____

Baseline Risk

Valvular heart disease No ☐ Yes ☐

If yes, specify the following for each applicable valve:

(check all valves that apply; for each checked, select one severity and for that severity indicate Insufficiency or Stenosis)

(If any severe, subject excluded)

☐ Mitral valve:	Trace	☐	If trace, specify:	Insufficiency	☐	Stenosis ☐
	Mild	☐	If mild, specify:	Insufficiency	☐	Stenosis ☐
	Moderate	☐	If mod, specify:	Insufficiency	☐	Stenosis ☐
	Severe	☐	If severe, specify:	Insufficiency	☐	Stenosis ☐
☐ Pulmonic valve:	Trace	☐	If trace, specify:	Insufficiency	☐	Stenosis ☐
	Mild	☐	If mild, specify:	Insufficiency	☐	Stenosis ☐
	Moderate	☐	If mod, specify:	Insufficiency	☐	Stenosis ☐
	Severe	☐	If severe, specify:	Insufficiency	☐	Stenosis ☐
☐ Tricuspid valve:	Trace	☐	If trace, specify:	Insufficiency	☐	Stenosis ☐
	Mild	☐	If mild, specify:	Insufficiency	☐	Stenosis ☐
	Moderate	☐	If mod, specify:	Insufficiency	☐	Stenosis ☐
	Severe	☐	If severe, specify:	Insufficiency	☐	Stenosis ☐
☐ Aortic valve:	Trace	☐	If trace, specify:	Insufficiency	☐	Stenosis ☐
	Mild	☐	If mild, specify:	Insufficiency	☐	Stenosis ☐
	Moderate	☐	If mod, specify:	Insufficiency	☐	Stenosis ☐
	Severe	☐	If severe, specify:	Insufficiency	☐	Stenosis ☐

If **Aortic Stenosis**, is valve area > 1.5 cm^2? Yes ☐ No ☐ ***(If No to AS > 1.5 cm^2, subject is excluded)***

Hospitalization for heart failure No ☐ Yes ☐

If yes, how many times in the past 12 months? _____

ED visits for heart failure No ☐ Yes ☐

If yes, how many times in the past 12 months? _____

Peripheral vascular disease No ☐ Yes ☐

Asymptomatic carotid disease No ☐ Yes ☐

Date of diagnosis of Anthracycline Induced Cardiomyopathy: _____

Procedure and Repair History

CABG No ☐ Yes ☐

If yes, how many operations have been performed? _____

If yes, date of most recent: _____

FORM NO. SEN011	
Acrostic Identifier:	
Study ID:	
Date source form completed (mm/dd/yyyy): _____/_____/_____	

Baseline Risk

PCI No ☐ Yes ☐

If yes, specify: Balloon only ☐ Stent ☐ Unknown ☐

If yes, date of most recent: _____

Valve repair No ☐ Yes ☐

If yes, check all that apply:

AV ☐
MV ☐
TV ☐
Pulmonic ☐

Valve replacement No ☐ Yes ☐

If yes, check all that apply:

AV ☐
MV ☐
TV ☐
Pulmonic ☐

If yes, specify: Artificial ☐ Bioprosthesis ☐ Unknown ☐

Oncologic Disease

Acute lymphatic leukemia No ☐ Yes ☐

If yes, date of diagnosis: _____

Breast cancer No ☐ Yes ☐

If yes, date of diagnosis: _____

Hodgkin's disease No ☐ Yes ☐

If yes, date of diagnosis: _____

Non-Hodgkin's lymphoma No ☐ Yes ☐

If yes, date of diagnosis: _____

Sarcomas No ☐ Yes ☐

If yes, date of diagnosis: _____

Other cancers *(only include malignant forms of cancer that require treatment, do not mention skin cancer unless melanoma)* No ☐ Yes ☐

If yes, specify type: _____

If yes, date of diagnosis: _____

Date of completion of most recent treatment: _____

FORM NO. SEN011	
Acrostic Identifier:	
Study ID:	
Date source form completed (mm/dd/yyyy): _____/_____/_____	

Baseline Risk

Antineoplastic Treatment

Anthracyclines (check all that apply):

- ☐ Doxorubicin — Cumulative dose (mg/m^2): _____
- ☐ Epirubicin — Cumulative dose (mg/m^2): _____
- ☐ Daunorubicin — Cumulative dose (mg/m^2): _____
- ☐ Idarubicin — Cumulative dose (mg/m^2): _____
- ☐ Liposomal doxorubicin — Cumulative dose (mg/m^2): _____
- ☐ Other (specify): _____ — Cumulative dose (mg/m^2): _____

Every attempt should be made to obtain the AIC exposure and report here as mg/m^2. Leave dose blank only if records are irretrievable.

Other potentially cardiotoxic agents (check all that apply):

- ☐ Her2 directed therapy
- ☐ Tyrosine kinase inhibitors
- ☐ Other (specify): _____

Other chemotherapies (check all that apply):

- ☐ Cyclophosphamide
- ☐ Cytoxan
- ☐ Paclitaxel (taxol)
- ☐ Taxotere
- ☐ Other (specify): _____

Radiation

☐ **Have never received radiation therapy**

Check all that apply:

- ☐ Whole breast — If checked, specify total grays: _____
- ☐ Partial breast — If checked, specify total grays: _____
- ☐ Post-mastectomy chest wall — If checked, specify total grays: _____
- ☐ Internal mammary field — If checked, specify total grays: _____
- ☐ Axillary — If checked, specify total grays: _____
- ☐ Mantle — If checked, specify total grays: _____
- ☐ Other (specify): _____ — If checked, specify total grays: _____

If radiation checked, please check here if left chest was included in the field: ☐

Comments:

Entered to eCRF ☐ Initials _____

FORM NO. SEN012

Acrostic Identifier:	
Study ID:	

Date source form completed (mm/dd/yyyy): _____/_____/_____

Physical Exam - Baseline

Date of exam (mm/dd/yyyy): _____/_____/_____

Vital Signs		NYHA Class:	
Height:	_____ ☐ inches ☐ centimeters	☐ I	***Subjects with a NYHA Class of I and IV will be ineligible for the study.***
Weight:	_____ ☐ pounds ☐ kilograms	☐ II	
Temperature:	__ __.__°F	☐ III	
Respirations:	__ __ breaths/minute	☐ IV	
Heart rate:	__ __ __ beats/minute		
Blood Pressure:	__ __ __ / __ __ __ mmHg (supine) SBP DBP		

Exam: If "Abnormal" is checked, please "Describe" the condition and also check if "Clinically Significant"

Organs	Not Examined	Normal	Abnormal	Clinically Significant	Describe
Skin	☐	☐	☐	☐	
HEENT	☐	☐	☐	☐	
Lungs	☐	☐	☐	☐	
CV	☐	☐	☐	☐	
Abdomen	☐	☐	☐	☐	
Lymph Nodes	☐	☐	☐	☐	
Musculoskeletal	☐	☐	☐	☐	
Neurological	☐	☐	☐	☐	
Renal	☐	☐	☐	☐	
Other: _____	☐	☐	☐	☐	

Device:

Does subject have an implantable cardiac device? Yes ☐ No ☐

If yes, complete the following:

Check the option that applies to the subject's device (check only 1 response):

- ☐ Pacemaker only
- ☐ ICD only
- ☐ Pacemaker plus ICD
- ☐ Biventricular pacing alone (CRT-P)
- ☐ Biventricular pacing with ICD (CRT-D)

Date of last device implantation (mm/yyyy): _____ Make/model of device: _____

FORM NO. SEN012	
Acrostic Identifier:	
Study ID:	
Date source form completed (mm/dd/yyyy): _____/_____/_____	

Physical Exam - Baseline

Questions:

Has the subject experienced any reportable (grade 2 or higher) adverse events since consent signed? *(If yes, complete AE form)*	Yes ☐ No ☐	
Was an ECG completed? *(If no or results clinically significant, please explain in Comments)*	Yes ☐ No ☐	***Please review AE reporting criteria to determine if an AE should also be submitted.***
If yes, were there clinically significant findings on the ECG?	Yes ☐ No ☐	

Please make sure the following tasks were completed:

- Infectious Disease lab panel drawn and sent for analysis
- MRI completed to send to the Core Lab
- ICD interrogation completed before and after the MRI (if applicable)

If a task was not (and will not be) completed, please note details in the Comments.

Comments:

Investigator Signature_____ Date:_____/_____/_____

Entered to eCRF ☐ Initials _____

FORM NO. SEN012	
Acrostic Identifier:	
Study ID:	
Date source form completed (mm/dd/yyyy): _____/_____/_____	

Physical Exam - Day 0 (Day of Injection)

Date of exam (mm/dd/yyyy): _____/_____/_____

Vital Signs	
Weight:	_____ ☐ pounds ☐ kilograms
Temperature:	__ __.__°F
Respirations:	__ __ breaths/minute
Heart rate:	__ __ __ beats/minute
Blood Pressure:	__ __ __ / __ __ __ mmHg (supine) SBP DBP

Exam: If "Abnormal" is checked, please "Describe" the condition and also check if "Clinically Significant"

Have changes occurred since previous visit? Yes ☐ No ☐ No exam done ☐ *If no or no exam done, table is complete.*

Organs	Not Examined	Normal	Abnormal	Clinically Significant	Describe
Skin	☐	☐	☐	☐	
HEENT	☐	☐	☐	☐	
Lungs	☐	☐	☐	☐	
CV	☐	☐	☐	☐	
Abdomen	☐	☐	☐	☐	
Lymph Nodes	☐	☐	☐	☐	
Musculoskeletal	☐	☐	☐	☐	
Neurological	☐	☐	☐	☐	
Renal	☐	☐	☐	☐	
Other: _____	☐	☐	☐	☐	

Questions:

Has the subject experienced any new reportable (grade 2 or higher) adverse events since the previous visit? *(If yes, complete AE form)*	Yes ☐ No ☐	
Have there been any changes to medications? *(If yes, update Medications form)*	Yes ☐ No ☐	***Please remember to update Medications form with inter-visit changes to medications.***
If subject was on anticoagulation therapy, was the INR checked per institutional guidelines and confirmed to be < 1.6 prior to the SPI procedure?	Yes ☐ No ☐ N/A ☐	***Check N/A if @ BSL pt not on ACT requiring INR checks.***

FORM NO. SEN012	
Acrostic Identifier:	
Study ID:	

Date source form completed (mm/dd/yyyy): _____/_____/_____

Physical Exam - Day 0 (Day of Injection)

Was a 2D Echo completed within 6 hours of SPI procedure? Yes ☐ No ☐
(If no or results clinically significant, please explain in Comments)

If yes, were there clinically significant findings on the 2D Echo? Yes ☐ No ☐

Was an ECG completed within 6 hours following the SPI procedure? Yes ☐ No ☐
(If no or results clinically significant, please explain in Comments)

If yes, were there clinically significant findings on the ECG? Yes ☐ No ☐

Please review AE reporting criteria to determine if an AE should also be submitted.

Please make sure the following tasks were completed:
- ICD interrogation completed before SPI (if applicable)
- 20ml of peripheral blood collected and prepared for shipment to the Core Lab (if applicable)

If a task was not (and will not be) completed, please note details in the Comments.

Comments:

Investigator Signature_____ Date:_____/_____/_____

Entered to eCRF ☐ Initials _____

FORM NO. SEN012

Acrostic Identifier:	
Study ID:	

Date source form completed (mm/dd/yyyy): _____/_____/_____

Physical Exam - Day 1 (Day after Injection)

Date of exam (mm/dd/yyyy): _____/_____/_____

Vital Signs	
Weight:	_____ ☐ pounds ☐ kilograms
Temperature:	__ __.__°F
Respirations:	__ __ breaths/minute
Heart rate:	__ __ __ beats/minute
Blood Pressure:	__ __ __ / __ __ __ mmHg (supine) SBP DBP

Reminder: Don't forget to provide the subject with a temperature log. Temperature should be monitored twice a day for 1 week. Log can be returned via mail or brought back at the 1 week visit.

Exam: If "Abnormal" is checked, please "Describe" the condition and also check if "Clinically Significant"

Have changes occurred since previous visit? Yes ☐ No ☐ No exam done ☐ *If no or no exam done, table is complete.*

Organs	Not Examined	Normal	Abnormal	Clinically Significant	Describe
Skin	☐	☐	☐	☐	
HEENT	☐	☐	☐	☐	
Lungs	☐	☐	☐	☐	
CV	☐	☐	☐	☐	
Abdomen	☐	☐	☐	☐	
Lymph Nodes	☐	☐	☐	☐	
Musculoskeletal	☐	☐	☐	☐	
Neurological	☐	☐	☐	☐	
Renal	☐	☐	☐	☐	
Other: _____	☐	☐	☐	☐	

Telemetry **(If intervention was required, select up to 3 rhythms that required intervention and describe intervention)**

Intervention required? Yes ☐ No ☐ ***If No, skip to the Questions section. If Yes, enter at least 1 intervention section below.***

If intervention was required, select arrhythmia that required intervention:

- ☐ Sinus tachycardia
- ☐ Supraventricular tachycardia
- ☐ Atrial fibrillation/flutter
- ☐ Junctional tachycardia/rhythm
- ☐ Accelerated idioventricular rhythm
- ☐ Ventricular fibrillation
- ☐ Multifocal atrial tachycardia
- ☐ Ventricular tachycardia

Describe intervention:

FORM NO. SEN012	
Acrostic Identifier:	
Study ID:	
Date source form completed (mm/dd/yyyy): _____/_____/_____	

Physical Exam - Day 1 (Day after Injection)

If intervention was required, select arrhythmia that required intervention:		Describe intervention:
☐ Sinus tachycardia	☐ Supraventricular tachycardia	
☐ Atrial fibrillation/flutter	☐ Junctional tachycardia/rhythm	
☐ Accelerated idioventricular rhythm	☐ Ventricular fibrillation	
☐ Multifocal atrial tachycardia	☐ Ventricular tachycardia	

If intervention was required, select arrhythmia that required intervention:		Describe intervention:
☐ Sinus tachycardia	☐ Supraventricular tachycardia	
☐ Atrial fibrillation/flutter	☐ Junctional tachycardia/rhythm	
☐ Accelerated idioventricular rhythm	☐ Ventricular fibrillation	
☐ Multifocal atrial tachycardia	☐ Ventricular tachycardia	

Questions:

Has the subject experienced any new reportable (grade 2 or higher) adverse events since the previous visit? *(If yes, complete AE form)*	Yes ☐ No ☐	
Have there been any changes to medications? *(If yes, update Medications form)*	Yes ☐ No ☐	***Please remember to update Medications form with inter-visit changes to medications.***
Was an ECG completed before discharge? *(If no or results clinically significant, please explain in Comments)*	Yes ☐ No ☐	***Please review AE reporting criteria to determine if an AE should also be submitted.***
If yes, were there clinically significant findings on the ECG?	Yes ☐ No ☐	
Please make sure the following task was completed: ◦ 20ml of peripheral blood collected and prepared for shipment to the Core Lab (if applicable)		***If task was not (and will not be) completed, please note details in the Comments.***

Comments:

Investigator Signature_____ Date:_____/_____/_____

Entered to eCRF ☐ Initials _____

FORM NO. SEN012

Acrostic Identifier:

Study ID:

Date source form completed (mm/dd/yyyy): _____/_____/_____

Physical Exam - Week 1

Date of exam (mm/dd/yyyy): _____/_____/_____

Vital Signs	
Weight:	_____ ☐ pounds ☐ kilograms
Temperature:	__ __.__°F
Respirations:	__ __ breaths/minute
Heart rate:	__ __ __ beats/minute
Blood Pressure:	___ ___ ___ / ___ ___ ___ mmHg (supine) SBP DBP

Exam: If "Abnormal" is checked, please "Describe" the condition and also check if "Clinically Significant"

Have changes occurred since previous visit? Yes ☐ No ☐ No exam done ☐ *If no or no exam done, table is complete.*

Organs	Not Examined	Normal	Abnormal	Clinically Significant	Describe
Skin	☐	☐	☐	☐	
HEENT	☐	☐	☐	☐	
Lungs	☐	☐	☐	☐	
CV	☐	☐	☐	☐	
Abdomen	☐	☐	☐	☐	
Lymph Nodes	☐	☐	☐	☐	
Musculoskeletal	☐	☐	☐	☐	
Neurological	☐	☐	☐	☐	
Renal	☐	☐	☐	☐	
Other: _____	☐	☐	☐	☐	

Questions:

Has the subject experienced any new reportable (grade 2 or higher) adverse events since the previous visit? *(If yes, complete AE form)*	Yes ☐ No ☐	
Have there been any changes to medications? *(If yes, update Medications form)*	Yes ☐ No ☐	***Please remember to update Medications form with inter-visit changes to medications.***
Was an ECG completed? *(If no or results clinically significant, please explain in Comments)*	Yes ☐ No ☐	***Please review AE reporting criteria to determine if an AE should also be submitted.***
If yes, were there clinically significant findings on the ECG?	Yes ☐ No ☐	

FORM NO. SEN012	
Acrostic Identifier:	
Study ID:	
Date source form completed (mm/dd/yyyy): _____/_____/_____	

Physical Exam - Week 1

Please make sure the following tasks were completed:

- 20ml of peripheral blood collected and prepared for shipment to the Core Lab (if applicable)
- Subject returned temperature log

If a task was not (and will not be) completed, please note details in the Comments.

Comments:

Investigator Signature_____ Date:_____/_____/_____

Entered to eCRF ☐ Initials _____

FORM NO. SEN012

Acrostic Identifier:	
Study ID:	

Date source form completed (mm/dd/yyyy): _____/_____/_____

Physical Exam - Month 1

Date of exam (mm/dd/yyyy): _____/_____/_____

Vital Signs		NYHA Class:	
Weight:	_____ ☐ pounds ☐ kilograms	☐ I	
Temperature:	__ __.__°F	☐ II	
Respirations:	__ __ breaths/minute	☐ III	
Heart rate:	__ __ __ beats/minute	☐ IV	
Blood Pressure:	___ ___ / ___ ___ mmHg (supine) SBP DBP	☐ Not assessed ***(If not assessed, explain in Comments)***	

Exam: If "Abnormal" is checked, please "Describe" the condition and also check if "Clinically Significant"

Have changes occurred since previous visit? Yes ☐ No ☐ No exam done ☐ *If no or no exam done, table is complete.*

Organs	Not Examined	Normal	Abnormal	Clinically Significant	Describe
Skin	☐	☐	☐	☐	
HEENT	☐	☐	☐	☐	
Lungs	☐	☐	☐	☐	
CV	☐	☐	☐	☐	
Abdomen	☐	☐	☐	☐	
Lymph Nodes	☐	☐	☐	☐	
Musculoskeletal	☐	☐	☐	☐	
Neurological	☐	☐	☐	☐	
Renal	☐	☐	☐	☐	
Other: _____	☐	☐	☐	☐	

Questions:

Has the subject experienced any new reportable (grade 2 or higher) adverse events since the previous visit? *(If yes, complete AE form)*	Yes ☐ No ☐	
Have there been any changes to medications? *(If yes, update Medications form)*	Yes ☐ No ☐	***Please remember to update Medications form with inter-visit changes to medications.***
Please make sure the following task was completed: ◦ 20ml of peripheral blood collected and prepared for shipment to the Core Lab (if applicable)		***If task was not (and will not be) completed, please note details in the Comments.***

FORM NO. SEN012	
Acrostic Identifier:	
Study ID:	
Date source form completed (mm/dd/yyyy): _____/_____/_____	

Physical Exam - Month 1

Comments:

Investigator Signature_____ Date:_____/_____/_____

Entered to eCRF ☐ Initials _____

FORM NO. SEN012

Acrostic Identifier:	
Study ID:	

Date source form completed (mm/dd/yyyy): _____/_____/_____

Physical Exam - Month 6

Date of exam (mm/dd/yyyy): _____/_____/_____

Vital Signs		NYHA Class:	
Weight:	_____ ☐pounds ☐kilograms	☐ I	
Temperature:	__ __.__°F	☐ II	
Respirations:	__ __ breaths/minute	☐ III	
Heart rate:	__ __ __ beats/minute	☐ IV	
Blood Pressure:	___ ___ / ___ ___ mmHg (supine) SBP DBP	☐ Not assessed ***(If not assessed, explain in Comments)***	

Exam: If "Abnormal" is checked, please "Describe" the condition and also check if "Clinically Significant"

Have changes occurred since previous visit? Yes ☐ No ☐ No exam done ☐ *If no or no exam done, table is complete.*

Organs	Not Examined	Normal	Abnormal	Clinically Significant	Describe
Skin	☐	☐	☐	☐	
HEENT	☐	☐	☐	☐	
Lungs	☐	☐	☐	☐	
CV	☐	☐	☐	☐	
Abdomen	☐	☐	☐	☐	
Lymph Nodes	☐	☐	☐	☐	
Musculoskeletal	☐	☐	☐	☐	
Neurological	☐	☐	☐	☐	
Renal	☐	☐	☐	☐	
Other: _____	☐	☐	☐	☐	

Questions:

Has the subject experienced any new reportable (grade 2 or higher) adverse events since the previous visit? *(If yes, complete AE form)*	Yes ☐ No ☐	
Have there been any changes to medications? *(If yes, update Medications form)*	Yes ☐ No ☐	***Please remember to update Medications form with inter-visit changes to medications.***

FORM NO. SEN012	
Acrostic Identifier:	
Study ID:	
Date source form completed (mm/dd/yyyy): _____/_____/_____	

Physical Exam - Month 6

Was an ECG completed? *(If no or results clinically significant, please explain in Comments)*	Yes ☐ No ☐	***Please review AE reporting criteria to determine if an AE should also be submitted.***
If yes, were there clinically significant findings on the ECG?	Yes ☐ No ☐	

Please make sure the following tasks were completed:

- MRI completed to send to the Core Lab
- ICD interrogation completed before and after the MRI (if applicable)
- 20ml of peripheral blood collected and prepared for shipment to the Core Lab (if applicable)

If a task was not (and will not be) completed, please note details in the Comments.

Comments:

Investigator Signature_____ Date:_____/_____/_____

Entered to eCRF ☐ Initials _____

FORM NO. SEN012	
Acrostic Identifier:	
Study ID:	
Date source form completed (mm/dd/yyyy): _____/_____/_____	

Physical Exam - Month 12

Date of exam (mm/dd/yyyy): _____/_____/_____

Vital Signs		**NYHA Class:**
Weight:	_____ ☐ pounds ☐ kilograms	☐ I
Temperature:	__ __.__ °F	☐ II
Respirations:	__ __ breaths/minute	☐ III
Heart rate:	__ __ __ beats/minute	☐ IV
Blood Pressure:	___ ___ / ___ ___ mmHg (supine) SBP DBP	☐ Not assessed ***(If not assessed, explain in Comments)***

Exam: If "Abnormal" is checked, please "Describe" the condition and also check if "Clinically Significant"

Have changes occurred since previous visit? Yes ☐ No ☐ No exam done ☐ *If no or no exam done, table is complete.*

Organs	Not Examined	Normal	Abnormal	Clinically Significant	Describe
Skin	☐	☐	☐	☐	
HEENT	☐	☐	☐	☐	
Lungs	☐	☐	☐	☐	
CV	☐	☐	☐	☐	
Abdomen	☐	☐	☐	☐	
Lymph Nodes	☐	☐	☐	☐	
Musculoskeletal	☐	☐	☐	☐	
Neurological	☐	☐	☐	☐	
Renal	☐	☐	☐	☐	
Other: _____	☐	☐	☐	☐	

Questions:

Has the subject experienced any new reportable (grade 2 or higher) adverse events since the previous visit? *(If yes, complete AE form)*	Yes ☐ No ☐	
Have there been any changes to medications? *(If yes, update Medications form)*	Yes ☐ No ☐	***Please remember to update Medications form with inter-visit changes to medications.***

FORM NO. SEN012	
Acrostic Identifier:	
Study ID:	

Date source form completed (mm/dd/yyyy): _____/_____/_____

Physical Exam - Month 12

Was an ECG completed? *(If no or results clinically significant, please explain in Comments)* Yes ☐ No ☐ ***Please review AE reporting criteria to determine if an AE should also be submitted.***

If yes, were there clinically significant findings on the ECG? Yes ☐ No ☐

Was follow-up documentation requested to assess the cancer status of the subject? *(If no, please explain in Comments)* Yes ☐ No ☐

If yes, what was the date of the evaluation (mm/dd/yyyy)?
(this is the date subject saw oncologist or post-cancer f/up care provider within 3 mos after study end) _____/_____/_____

Reminder: If the subject has not yet had their SOC visit, please be sure to click the "Save Incomplete" button.

If yes, please indicate outcome of the evaluation: *(select only 1 option)*
- ☐ A. No active cancer or recurrence is suspected
- ☐ B. Uncertain if any active cancer or recurrence is present
- ☐ C. Active cancer or recurrence was detected

If B selected, please enter date of test(s) indicating possible active disease (mm/dd/yyyy): ____/____/_____

If B selected, please include any pending tests/scans/biopsies:

If C selected, please indicate detection date (mm/dd/yyyy): ____/____/_____

If C selected, please include tests/scans/biopsies that led to detection:

Please make sure the following tasks were completed:
- MRI completed to send to the Core Lab
- ICD interrogation completed before and after the MRI (if appliacble)

If a task was not (and will not be) completed, please note details in the Comments.

Comments:

Investigator Signature_____ Date:_____/_____/_____

Entered to eCRF ☐ Initials _____

FORM NO. SEN012	
Acrostic Identifier:	
Study ID:	
Date source form completed (mm/dd/yyyy): _____/_____/_____	

Physical Exam - Interim

Date of exam (mm/dd/yyyy): _____/_____/_____

Vital Signs		**NYHA Class:**
Weight:	_____ ☐ pounds ☐ kilograms	☐ I
Temperature:	__ __.__ °F	☐ II
Respirations:	__ __ breaths/minute	☐ III
Heart rate:	__ __ __ beats/minute	☐ IV
Blood Pressure:	___ ___ ___ / ___ ___ ___ mmHg (supine) SBP DBP	☐ Not assessed ***(If not assessed, explain in Comments)***

Exam: If "Abnormal" is checked, please "Describe" the condition and also check if "Clinically Significant"

Organs	Not Examined	Normal	Abnormal	Clinically Significant	Describe
Skin	☐	☐	☐	☐	
HEENT	☐	☐	☐	☐	
Lungs	☐	☐	☐	☐	
CV	☐	☐	☐	☐	
Abdomen	☐	☐	☐	☐	
Lymph Nodes	☐	☐	☐	☐	
Musculoskeletal	☐	☐	☐	☐	
Neurological	☐	☐	☐	☐	
Renal	☐	☐	☐	☐	
Other: _____	☐	☐	☐	☐	

Questions:

Has the subject experienced any new reportable (grade 2 or higher) adverse events since the previous visit? *(If yes, complete AE form)*	Yes ☐ No ☐	
Have there been any changes to medications? *(If yes, update medication form)*	Yes ☐ No ☐	***Please remember to update Medication form with inter-visit changes to medications.***
Comments:		

Investigator Signature_____ Date:_____/_____/_____

Entered to eCRF ☐ Initials _____

FORM NO. SEN014	
Acrostic Identifier:	
Study ID:	

Medications

Enter or update medication information here. To add a medication, click the "Add New Medication" button, enter medication information, and click "Add". Repeat for each medication. Medications will be listed in a table below as they are entered. To modify medication information, click "Select" to the right of the medication in the table, edit the information and click 'Update'. On the first form entered, a response must be given to the "At baseline, is subject on an anticoagulation medication that requires an institutional INR check?" question.

At baseline, is subject on an anticoagulation medication that requires an institutional INR check? **No** ☐ **Yes** ☐

	Date Source Form Completed	Medication Name	Dose	Unit	Frequency	Prior to Study Start	Start Date	Stop Date	Comments
1						☐			
2						☐			
3						☐			
4						☐			
5						☐			
6						☐			
7						☐			
8						☐			
9						☐			
10						☐			
11						☐			
12						☐			
13						☐			
14						☐			
15						☐			
16						☐			
17						☐			
18						☐			
19						☐			
20						☐			

Comments:

Entered to eCRF ☐ Initials _____

FORM NO. SEN015			
Acrostic Identifier:			
Study ID:			
Date source form completed (mm/dd/yyyy): ____/____/_____			
Medication Allergies			
Drug Allergies:	NKDA ☐	Yes ☐	If yes, please list:
Comments:			

Entered to eCRF ☐ Initials _____

FORM NO. SEN016	
Acrostic Identifier:	
Study ID:	
Adverse Events	
Date source form completed (mm/dd/yyyy): ____/____/_____	
Date of onset (mm/dd/yyyy): ____/____/__	Resolved date (mm/dd/yyyy): ____/____/_____
Date site learned of the event (mm/dd/yyyy): ____/____/_____	
Report all AEs rated as severity grade 2 or higher (per CTCAE version 4.0) unless exempt from AE reporting/recording per protocol. (CTCAE=Common Terminology Criteria for Adverse Events)	
1. Adverse event:	
2. Severity: Grade 1 - Mild (not entered in database) ☐ Grade 2 - Moderate ☐ Grade 3 - Severe ☐ Grade 4 - Life Threatening or Disabling ☐ Grade 5 - Death	
3. Was this event expected? ☐ Yes ☐ No	*Please refer to the Investigators Brochure/Informed Consent Form. Medical Monitor will be making final determination of expectedness for the purposes of reporting to the DSMB and FDA.*
4. Was the patient hospitalized > 24 hours? ☐ Yes ☐ No	
4a. Admission date (mm/dd/yyyy): ____/____/_____	
4b. Admission diagnosis:	
4c. Date of discharge (mm/dd/yyyy): ____/____/_____	
4d. Discharge diagnosis:	
5. Related to study procedure: (Check only one)	☐ Study product injection ☐ MRI ☐ 6 minute walk test ☐ Not related to study procedure
6. Relationship to study treatment/procedure: (Check only one)	☐ Unrelated ☐ Unlikely ☐ Possibly ☐ Probably ☐ Definitely related
7. Outcome: (Check only one)	☐ Resolved or stabilized without sequelae ☐ Resolved or stabilized with sequelae ☐ Ongoing ☐ Death: AE present at death, but not cause ☐ Death: death due to AE

FORM NO. SEN016

Acrostic Identifier:

Study ID:

Adverse Events

8. Was this a Serious Adverse Event (SAE)? *(see #9 below)* ☐ Yes ☐ No

If yes to #8 and yes or no to #8a, rest of form is required.
If no to #8 & yes to #8a, skip to number 10.
If no to #8 and #8a, skip to "PI review AE".

a. Was this event a Clinical Endpoint (CE)? ☐ Yes ☐ No

Complete for Serious Adverse Event Only:

Date AE progressed to SAE (mm/dd/yyyy): ____/____/_____

Date site learned AE progressed to SAE (mm/dd/yyyy): ____/____/_____

Note: If event starts as a SAE, enter "Date of onset" in these date fields

9. Indicate the outcome or nature of the event that defines it as a Serious Adverse Event (SAE):
(Check all that apply)

☐ Resulted in death

9.a.1 If death, enter the date (mm/dd/yyyy) of death:
____/____/_____

9.a.2 Was an autopsy performed?
☐ Yes ☐ No ☐ Unknown

☐ Was life-threatening
☐ Required hospitalization or prolongation of existing hospitalization
☐ Resulted in persistent or significant disability/incapacity
☐ Resulted in a congenital anomaly/birth defect
☐ Other important medical event

10. Describe the clinical history of the SAE/CE:

11. Describe the associated signs and symptoms of the SAE/CE:

12. Specify what the event is related to if not the study product (e.g. study procedure, other conditions/illness):

13. Describe relevant past medical history:

14. Describe the medical management for the SAE/CE:

15. Record abnormal diagnostic studies relevant to SAE/CE:
Note: If not applicable, enter "none"

16. Is the patient currently taking medication in response to SAE/CE? ☐ Yes ☐ No
If Yes, confirm that all medications have been reported on the Medications form.

FORM NO. SEN016	
Acrostic Identifier:	
Study ID:	
Adverse Events	
Comments:	
☐ PI reviewed AE	Date PI reviewed AE (mm/dd/yyyy): ____/____/_____
☐ PI reviewed SAE/CE	Date PI reviewed SAE/CE (mm/dd/yyyy): ____/____/_____
Note: Only required if event is a SAE/CE or if AE progressed to SAE/CE	

PI Signature _____ Date: ____/____/_____

Entered to eCRF ☐ Initials _____

1. Major adverse cardiac events (MACE) including: death, hospitalization for worsening heart failure (HF), and/or other exacerbation of HF (non-hospitalization)
2. Other significant clinical events including: non-fatal stroke, non-fatal myocardial infarction, coronary artery revascularization, ventricular tachycardia/fibrillation, pericardial tamponade, infectious myocarditis, hypersensitivity reaction, neoplasm, and/or any other potential deleterious late effects detected and corroborated by clinical presentation, laboratory investigations, image analysis, and when necessary with biopsy from suspected target sites in the body

FORM NO. SEN016

Acrostic Identifier:

Study ID:

Adverse Events

Date source form completed (mm/dd/yyyy): ____/____/_____

Date of onset (mm/dd/yyyy): ____/____/___ | Resolved date (mm/dd/yyyy): ____/____/_____

Date site learned of the event (mm/dd/yyyy): ____/____/_____

Report all AEs rated as severity grade 2 or higher (per CTCAE version 4.0) unless exempt from AE reporting/recording per protocol. (CTCAE=Common Terminology Criteria for Adverse Events)

1. Adverse event:

2. Severity:
Grade 1 - Mild (not entered in database)
☐ Grade 2 - Moderate
☐ Grade 3 - Severe
☐ Grade 4 - Life Threatening or Disabling
☐ Grade 5 - Death

3. Was this event expected? ☐ Yes ☐ No *Please refer to the Investigators Brochure/Informed Consent Form. Medical Monitor will be making final determination of expectedness for the purposes of reporting to the DSMB and FDA.*

4. Was the patient hospitalized > 24 hours? ☐ Yes ☐ No

4a. Admission date (mm/dd/yyyy): ____/____/_____

4b. Admission diagnosis:

4c. Date of discharge (mm/dd/yyyy): ____/____/_____

4d. Discharge diagnosis:

5. Related to study procedure: (Check only one)
☐ Study product injection
☐ MRI
☐ 6 minute walk test
☐ Not related to study procedure

6. Relationship to study treatment/procedure: (Check only one)
☐ Unrelated
☐ Unlikely
☐ Possibly
☐ Probably
☐ Definitely related

7. Outcome: (Check only one)
☐ Resolved or stabilized without sequelae
☐ Resolved or stabilized with sequelae
☐ Ongoing
☐ Death: AE present at death, but not cause
☐ Death: death due to AE

FORM NO. SEN016

Acrostic Identifier:

Study ID:

Adverse Events

8. Was this a Serious Adverse Event (SAE)? *(see #9 below)* ☐ Yes ☐ No

a. Was this event a *possible* Clinical Endpoint (CE)? ☐ Yes ☐ No

If yes to #8 and yes or no to #8a, rest of form is required.
If no to #8 & yes to #8a, skip to number 10.
If no to #8 and #8a, skip to "PI review AE".

Note: Selecting yes to a possible CE is a flag that sends the event for adjudication to our outside experts; it does not mean the event is indeed a clinical endpoint.

Complete for Serious Adverse Event Only:

Date AE progressed to SAE (mm/dd/yyyy): ____/____/_____

Date site learned AE progressed to SAE (mm/dd/yyyy): ____/____/_____

Note: If event starts as a SAE, enter "Date of onset" in these date fields

9. Indicate the outcome or nature of the event that defines it as a Serious Adverse Event (SAE):
(Check all that apply)

- ☐ Resulted in death
  - 9.a.1 If death, enter the date (mm/dd/yyyy) of death: ____/____/_____
  - 9.a.2 Was an autopsy performed? ☐ Yes ☐ No ☐ Unknown
- ☐ Was life-threatening
- ☐ Required hospitalization or prolongation of existing hospitalization
- ☐ Resulted in persistent or significant disability/incapacity
- ☐ Resulted in a congenital anomaly/birth defect
- ☐ Other important medical event

10. Describe the clinical history of the SAE/CE:

11. Describe the associated signs and symptoms of the SAE/CE:

12. Specify what the event is related to if not the study product (e.g. study procedure, other conditions/illness):

13. Describe relevant past medical history:

14. Describe the medical management for the SAE/CE:

FORM NO. SEN016
Acrostic Identifier:
Study ID:

Adverse Events

15. Record abnormal diagnostic studies relevant to SAE/CE:
Note: If not applicable, enter "none"

16. Is the patient currently taking medication in response to SAE/CE? ☐ Yes ☐ No
If Yes, confirm that all medications have been reported on the Medications form.

Comments:

☐ PI reviewed AE Date PI reviewed AE (mm/dd/yyyy): ____/____/_____

☐ PI reviewed SAE/CE Date PI reviewed SAE/CE (mm/dd/yyyy): ____/____/_____

Note: Only required if event is a SAE/CE or if AE progressed to SAE/CE

PI Signature _____ Date: ____/____/_____

Entered to eCRF ☐ Initials _____

1. Major adverse cardiac events (MACE) including: death, hospitalization for worsening heart failure (HF), and/or other exacerbation of HF (non-hospitalization)
2. Other significant clinical events including: non-fatal stroke, non-fatal myocardial infarction, coronary artery revascularization, ventricular tachycardia/fibrillation, pericardial tamponade, infectious myocarditis, hypersensitivity reaction, neoplasm, and/or any other potential deleterious late effects detected and corroborated by clinical presentation, laboratory investigations, image analysis, and when necessary with biopsy from suspected target sites in the body

FORM NO. SEN017	
Acrostic Identifier:	
Study ID:	

Date source form completed (mm/dd/yyyy): _____/_____/_____

Laboratory Tests - Baseline

Date specimen obtained (mm/dd/yyyy): ____/____/____

CBC with Differential	**Result**	**Unit**	**Normal Range**	**">" or "<"**
WBC		K/mm^3	3.6-11.0 K/mm^3	
RBC		M/mm^3	3.71-5.9 M/mm^3	
Hgb		gm/dL	11-17.7 gm/dL	
Hct		%	33-54%	
MCV		fL	78-100 fL	
Platelets		K/mm^3	140-450 K/mm^3	
WBC Differential				
Neutrophilis		%	35-85%	
Lymphocytes		%	10-65%	
Monocytes		%	0-13%	
Eosinophils		%	0-8%	
Basophils		%	0-3.0%	<
Chemistry Tests				
Na+		mmol/L	135-148 mmol/L	
K+		mmol/L	3.3-5.5 mmol/L	
Chloride		mmol/L	96-109 mmol/L	
CO_2		mmol/L	19-34 mmol/L	
Glucose		mg/dL	40-200 mg/dL	
BUN		mg/dL	5-26 mg/dL	
Creatinine		mg/dL	0.4-1.27 mg/dL	<
eGFR		$ml/min/1.73m^2$	60-180	>
Liver Functions				
Bilirubin-Total		mg/dL	0.0-1.2 mg/dL	<
Bilirubin-Direct		mg/dL	0.0-0.5 mg/dL	<
Total Protein		g/dL	5.4-9.0 g/dL	
Albumin		g/dL	3.3-5.2 g/dL	
ALT		U/L	0.0-60 U/L	<
AST		U/L	0.0-40 U/L	<
Alkaline Phosphatase		U/L	20-136 U/L	<

FORM NO. SEN017				
Acrostic Identifier:				
Study ID:				
Date source form completed (mm/dd/yyyy): _____/_____/_____				
Laboratory Tests - Baseline				
Cardiac Markers (Either Troponin T or Troponin I should be completed, NOT both)				
Troponin T		ng/ml	0.0-10 ng/ml	<
Troponin I		ng/ml	0.0-100 ng/ml	<
Other Tests				
NT-proBNP		pg/ml	0-2,000 pg/ml	
HbA1c		%	4.0-6.9 %	<
INR		seconds	< 1.2	< and >
PTT		seconds	23-42.2 secs	
PRA		%	0-99%	
PT		seconds	0.9-14.9	<
Pregnancy Test (women of childbearing potential) ☐ Not applicable/Not done			Negative (urine) < 5.0 mU/ml (quantitative blood)	
Infectious Diseases				
Infectious disease tests collected ☐				
Comments:				
☐ Investigator reviewed Lab report		Date Investigator reviewed (mm/dd/yyyy): ___/___/___		

Entered to eCRF ☐ Initials _____

FORM NO. SEN017				
Acrostic Identifier:				
Study ID:				
Date source form completed (mm/dd/yyyy): _____/_____/_____				
Laboratory Tests - Day 0 (Day of Injection)				
Pre-NOGA	**Date (mm/dd/yyyy):** ____/____/____ **Time (hhmm):** __ __ __ __			
CBC with Differential	**Result**	**Unit**	**Normal Range**	**">" or "<"**
WBC		K/mm^3	3.6-11.0 K/mm^3	
RBC		M/mm^3	3.71-5.9 M/mm^3	
Hgb		gm/dL	11-17.7 gm/dL	
Hct		%	33-54%	
MCV		fL	78-100 fL	
Platelets		K/mm^3	140-450 K/mm^3	
WBC Differential				
Neutrophilis		%	35-85%	
Lymphocytes		%	10-65%	
Monocytes		%	0-13%	
Eosinophils		%	0-8%	
Basophils		%	0-3.0%	<
Chemistry Tests				
Na+		mmol/L	135-148 mmol/L	
K+		mmol/L	3.3-5.5 mmol/L	
Chloride		mmol/L	96-109 mmol/L	
CO_2		mmol/L	19-34 mmol/L	
Glucose		mg/dL	40-200 mg/dL	
BUN		mg/dL	5-26 mg/dL	
Creatinine		mg/dL	0.4-1.27 mg/dL	<
eGFR		$ml/min/1.73m^2$	60-180	>
Cardiac Markers (Either Troponin T or Troponin I should be completed, NOT both)				
Troponin T		ng/ml	0.0-10 ng/ml	
Troponin I		ng/ml	0.0-100 ng/ml	
Post-NOGA	**Date (mm/dd/yyyy):** ____/____/____ **Time (hhmm):** __ __ __ __			
CBC with Differential	**Result**	**Unit**	**Normal Range**	**">" or "<"**
WBC		K/mm^3	3.6-11.0 K/mm^3	
RBC		M/mm^3	3.71-5.9 M/mm^3	
Hgb		gm/dL	11-17.7 gm/dL	
Hct		%	33-54%	
MCV		fL	78-100 fL	
Platelets		K/mm^3	140-450 K/mm^3	

FORM NO. SEN017				
Acrostic Identifier:				
Study ID:				
Date source form completed (mm/dd/yyyy): _____/_____/_____				
Laboratory Tests - Day 0 (Day of Injection)				
WBC Differential				
Neutrophilis		%	35-85%	
Lymphocytes		%	10-65%	
Monocytes		%	0-13%	
Eosinophils		%	0-8%	
Basophils		%	0-3.0%	<
Cardiac Markers (Either Troponin T or Troponin I should be completed, NOT both)				
Troponin T		ng/ml	0.0-10 ng/ml	
Troponin I		ng/ml	0.0-100 ng/ml	
Other Tests				
Pregnancy Test (women of childbearing potential) ☐ Not applicable/Not done			Negative (urine) < 5.0 mU/ml (quantitative blood)	
Comments:				
☐ Investigator reviewed Lab report		Date Investigator reviewed (mm/dd/yyyy): ___/___/___		

Entered to eCRF ☐ Initials _____

FORM NO. SEN017				
Acrostic Identifier:				
Study ID:				
Date source form completed (mm/dd/yyyy): _____/_____/_____				
Laboratory Tests - Day 1 (Day after Injection)				
Date specimen obtained (mm/dd/yyyy): ____/____/____				
CBC with Differential	**Result**	**Unit**	**Normal Range**	**">" or "<"**
WBC		K/mm^3	3.6-11.0 K/mm^3	
RBC		M/mm^3	3.71-5.9 M/mm^3	
Hgb		gm/dL	11-17.7 gm/dL	
Hct		%	33-54%	
MCV		fL	78-100 fL	
Platelets		K/mm^3	140-450 K/mm^3	
WBC Differential				
Neutrophilis		%	35-85%	
Lymphocytes		%	10-65%	
Monocytes		%	0-13%	
Eosinophils		%	0-8%	
Basophils		%	0-3.0%	<
Chemistry Tests				
Na+		mmol/L	135-148 mmol/L	
K+		mmol/L	3.3-5.5 mmol/L	
Chloride		mmol/L	96-109 mmol/L	
CO_2		mmol/L	19-34 mmol/L	
Glucose		mg/dL	40-200 mg/dL	
BUN		mg/dL	5-26 mg/dL	
Creatinine		mg/dL	0.4-1.27 mg/dL	<
eGFR		$ml/min/1.73m^2$	60-180	>
Cardiac Markers (Either Troponin T or Troponin I should be completed, NOT both)				
Prior to discharge	**Date (mm/dd/yyyy):** ____/____/____ **Time (hhmm):** __ __ __ __			
Troponin T		ng/ml	0.0-10 ng/ml	<
Troponin I		ng/ml	0.0-100 ng/ml	<
Comments:				
☐ Investigator reviewed Lab report Date Investigator reviewed (mm/dd/yyyy): ___/___/___				

Entered to eCRF ☐ Initials _____

FORM NO. SEN017				
Acrostic Identifier:				
Study ID:				
Date source form completed (mm/dd/yyyy): _____/_____/_____				
Laboratory Tests - Week 1				
Date specimen obtained (mm/dd/yyyy): ____/____/____				
CBC with Differential	**Result**	**Unit**	**Normal Range**	**">" or "<"**
WBC		K/mm^3	3.6-11.0 K/mm^3	
RBC		M/mm^3	3.71-5.9 M/mm^3	
Hgb		gm/dL	11-17.7 gm/dL	
Hct		%	33-54%	
MCV		fL	78-100 fL	
Platelets		K/mm^3	140-450 K/mm^3	
WBC Differential				
Neutrophilis		%	35-85%	
Lymphocytes		%	10-65%	
Monocytes		%	0-13%	
Eosinophils		%	0-8%	
Basophils		%	0-3.0%	<
Chemistry Tests				
Na+		mmol/L	135-148 mmol/L	
K+		mmol/L	3.3-5.5 mmol/L	
Chloride		mmol/L	96-109 mmol/L	
CO_2		mmol/L	19-34 mmol/L	
Glucose		mg/dL	40-200 mg/dL	
BUN		mg/dL	5-26 mg/dL	
Creatinine		mg/dL	0.4-1.27 mg/dL	<
eGFR		$ml/min/1.73m^2$	60-180	>
Cardiac Markers (Either Troponin T or Troponin I should be completed, NOT both)				
Troponin T		ng/ml	0.0-10 ng/ml	<
Troponin I		ng/ml	0.0-100 ng/ml	<
Comments:				
☐ Investigator reviewed Lab report		Date Investigator reviewed (mm/dd/yyyy): ___/___/___		

Entered to eCRF ☐ Initials _____

FORM NO. SEN017				
Acrostic Identifier:				
Study ID:				
Date source form completed (mm/dd/yyyy): _____/_____/_____				
Laboratory Tests - Month 1				
Date specimen obtained (mm/dd/yyyy): ____/____/____				
CBC with Differential	**Result**	**Unit**	**Normal Range**	**">" or "<"**
WBC		K/mm^3	3.6-11.0 K/mm^3	
RBC		M/mm^3	3.71-5.9 M/mm^3	
Hgb		gm/dL	11-17.7 gm/dL	
Hct		%	33-54%	
MCV		fL	78-100 fL	
Platelets		K/mm^3	140-450 K/mm^3	
WBC Differential				
Neutrophilis		%	35-85%	
Lymphocytes		%	10-65%	
Monocytes		%	0-13%	
Eosinophils		%	0-8%	
Basophils		%	0-3.0%	<
Chemistry Tests				
Na+		mmol/L	135-148 mmol/L	
K+		mmol/L	3.3-5.5 mmol/L	
Chloride		mmol/L	96-109 mmol/L	
CO_2		mmol/L	19-34 mmol/L	
Glucose		mg/dL	40-200 mg/dL	
BUN		mg/dL	5-26 mg/dL	
Creatinine		mg/dL	0.4-1.27 mg/dL	<
eGFR		$ml/min/1.73m^2$	60-180	>
Other Tests				
PRA		%	0-99%	
Comments:				
☐ Investigator reviewed Lab report		Date Investigator reviewed (mm/dd/yyyy): ___/___/___		

Entered to eCRF ☐ Initials _____

FORM NO. SEN017				
Acrostic Identifier:				
Study ID:				
Date source form completed (mm/dd/yyyy): _____/_____/_____				
Laboratory Tests - Month 6 and Month 12				
Date specimen obtained (mm/dd/yyyy): ____/____/____ **Visit Type:**				
CBC with Differential	**Result**	**Unit**	**Normal Range**	**">" or "<"**
WBC		K/mm^3	3.6-11.0 K/mm^3	
RBC		M/mm^3	3.71-5.9 M/mm^3	
Hgb		gm/dL	11-17.7 gm/dL	
Hct		%	33-54%	
MCV		fL	78-100 fL	
Platelets		K/mm^3	140-450 K/mm^3	
WBC Differential				
Neutrophilis		%	35-85%	
Lymphocytes		%	10-65%	
Monocytes		%	0-13%	
Eosinophils		%	0-8%	
Basophils		%	0-3.0%	<
Chemistry Tests				
Na+		mmol/L	135-148 mmol/L	
K+		mmol/L	3.3-5.5 mmol/L	
Chloride		mmol/L	96-109 mmol/L	
CO_2		mmol/L	19-34 mmol/L	
Glucose		mg/dL	40-200 mg/dL	
BUN		mg/dL	5-26 mg/dL	
Creatinine		mg/dL	0.4-1.27 mg/dL	<
eGFR		$ml/min/1.73m^2$	60-180	>
Liver Functions				
Bilirubin-Total		mg/dL	0.0-1.2 mg/dL	<
Bilirubin-Direct		mg/dL	0.0-0.5 mg/dL	<
Total Protein		g/dL	5.4-9.0 g/dL	
Albumin		g/dL	3.3-5.2 g/dL	
ALT		U/L	0.0-60 U/L	<
AST		U/L	0.0-40 U/L	<
Alkaline Phosphatase		U/L	20-136 U/L	<

FORM NO. SEN017				
Acrostic Identifier:				
Study ID:				
Date source form completed (mm/dd/yyyy): _____/_____/_____				
Laboratory Tests - Month 6 and Month 12				
Other Tests				
NT-proBNP		pg/ml	0-2,000 pg/ml	
HbA1c		%	4.0-6.9 %	<
PRA		%	0-99%	
Pregnancy Test (women of childbearing potential) ☐ Not applicable/Not done			Negative (urine) < 5.0 mU/ml (quantitative blood)	
Comments:				
☐ Investigator reviewed Lab report		Date Investigator reviewed (mm/dd/yyyy): ___/___/___		

Entered to eCRF ☐ Initials _____

FORM NO. SEN017				
Acrostic Identifier:				
Study ID:				
Date source form completed (mm/dd/yyyy): _____/_____/_____				
Laboratory Tests - Interim				
Date specimen obtained (mm/dd/yyyy): ____/____/____				
CBC with Differential	**Result**	**Unit**	**Normal Range**	**">" or "<"**
WBC		K/mm^3	3.6-11.0 K/mm^3	
RBC		M/mm^3	3.71-5.9 M/mm^3	
Hgb		gm/dL	11-17.7 gm/dL	
Hct		%	33-54%	
MCV		fL	78-100 fL	
Platelets		K/mm^3	140-450 K/mm^3	
WBC Differential				
Neutrophilis		%	35-85%	
Lymphocytes		%	10-65%	
Monocytes		%	0-13%	
Eosinophils		%	0-8%	
Basophils		%	0-3.0%	<
Chemistry Tests				
Na+		mmol/L	135-148 mmol/L	
K+		mmol/L	3.3-5.5 mmol/L	
Chloride		mmol/L	96-109 mmol/L	
CO_2		mmol/L	19-34 mmol/L	
Glucose		mg/dL	40-200 mg/dL	
BUN		mg/dL	5-26 mg/dL	
Creatinine		mg/dL	0.4-1.27 mg/dL	<
eGFR		$ml/min/1.73m^2$	60-180	>
Liver Functions				
Bilirubin-Total		mg/dL	0.0-1.2 mg/dL	<
Bilirubin-Direct		mg/dL	0.0-0.5 mg/dL	<
Total Protein		g/dL	5.4-9.0 g/dL	
Albumin		g/dL	3.3-5.2 g/dL	
ALT		U/L	0.0-60 U/L	<
AST		U/L	0.0-40 U/L	<
Alkaline Phosphatase		U/L	20-136 U/L	<

FORM NO. SEN017				
Acrostic Identifier:				
Study ID:				
Date source form completed (mm/dd/yyyy): _____/_____/_____				
Laboratory Tests - Interim				
Cardiac Markers (Either Troponin T or Troponin I should be completed, NOT both)				
Troponin T		ng/ml	0.0-10 ng/ml	<
Troponin I		ng/ml	0.0-100 ng/ml	<
Other Tests				
NT-proBNP		pg/ml	0-2,000 pg/ml	
HbA1c		%	4.0-6.9 %	<
INR		seconds	< 1.2	< and >
PTT		seconds	23-42.2 secs	
PRA		%	0-99%	
PT		seconds	0.9-14.9	<
Pregnancy Test (women of childbearing potential) ☐ Not applicable/Not done			Negative (urine) < 5.0 mU/ml (quantitative blood)	
Comments:				
☐ Investigator reviewed Lab report		Date Investigator reviewed (mm/dd/yyyy): ___/___/___		

Entered to eCRF ☐ Initials _____

FORM NO. SEN018	
Acrostic Identifier:	
Study ID:	

Missing Form

	Form Missing:	Reason/Comment:	Date of this Report:
☐	Baseline - Physical Exam		
☐	Baseline - Labs		
☐	Baseline - Risk		
☐	Baseline - MLHFQ		
☐	Baseline - 6 Min Walk		
☐	Medication Allergies		
☐	Medications		
☐	Eligibility		
☐	Treatment Checklist		
☐	Day 0 - Physical Exam		
☐	Day 0 - Labs		
☐	Day 0 - Study Product Injection		
☐	Day 1 - Physical Exam		
☐	Day 1 - Labs		
☐	Wk 1 - Physical Exam		
☐	Wk 1 - Labs		
☐	Mo 1 - Physical Exam		
☐	Mo 1 - Labs		
☐	Mo 6 - Physical Exam		
☐	Mo 6 - Labs		
☐	Mo 6 - MLHFQ		
☐	Mo 6 - 6 Minute Walk		
☐	Mo 12 - Physical Exam		
☐	Mo 12 - Labs		
☐	Mo 12 - MLHFQ		
☐	Mo 12 - 6 Minute Walk		
☐	Mo 24 - F/U Phone Contact		
☐	End of Study		

FORM NO. SEN020	
Acrostic Identifier:	
Study ID:	
Six Minute Walk Test - Baseline, Month 6, and Month 12	
Date source form completed (mm/dd/yyyy): _____/_____/_____	
Visit Type:	
Date of walk test (mm/dd/yyyy): _____/_____/_____	*If date of tests and/or who performs the tests differ, please put a note in the Comments.*
Tests performed by: _____	
Heart rate:__ __ __ beats/minute	
Blood pressure: __ __ __ /__ __ __ mmHg (supine) SBP DBP	

TEST 1 START OF TEST	**TEST 1 END OF TEST**
Borg rating of shortness of breath: _____	Borg rating of shortness of breath: _____
Borg rating of overall fatigue: _____	Borg rating of overall fatigue: _____
Start time (hhmm): __ __ __ ___	Stop time (hhmm): __ __ __ __
Stopped or paused? ☐ Yes ☐ No *If yes, see next.*	
What if anything, kept the subject from walking further?	
Total distance walked _____ meters (T1)	*Enter 0 if subject unable to attempt; explain in Comments box for T1.*
Comments for T1:	

TEST 2 START OF TEST	**TEST 2 END OF TEST**
Borg rating of shortness of breath: _____	Borg rating of shortness of breath: _____
Borg rating of overall fatigue: _____	Borg rating of overall fatigue: _____
Start time (hhmm): __ __ __ ___	Stop time (hhmm): __ __ __ __
Stopped or paused? ☐ Yes ☐ No *If yes, see next.*	
What if anything, kept the subject from walking further?	

FORM NO. SEN020	
Acrostic Identifier:	
Study ID:	
Six Minute Walk Test - Baseline, Month 6, and Month 12	
Total distance walked _____ meters (T2)	*Enter 0 if subject unable to attempt; explain in Comments box for T2.*
Comments for T2:	
After T2, calculate the % change between T1 and T2 for total distance walked. If > 10%, Test 3 is required.	***Calculation:*** **[|T1-T2| / Max(T1, T2)] * 100**
% change: _____ %	*Shaded fields are filled in by 6 MWT eCRF programming.*

TEST 3 START OF TEST	**TEST 3 END OF TEST**
Borg rating of shortness of breath: _____	Borg rating of shortness of breath: _____
Borg rating of overall fatigue: _____	Borg rating of overall fatigue: _____
Start time (hhmm): __ __ __ ___	Stop time (hhmm): __ __ __ __
Stopped or paused? ☐ Yes ☐ No *If yes, see next.*	
What if anything, kept the subject from walking further?	
Total distance walked _____ meters (T3)	*Enter 0 if subject unable to attempt; explain in Comments box for T3.*
Comments for T3:	
Comments:	

Entered to eCRF ☐ Initials _____

FORM NO. SEN023			
Acrostic Identifier:			
Study ID:			
Date source form completed (mm/dd/yyyy): _____/_____/_____			
Eligibility Criteria			
	Y	**N**	**Inclusion Criteria (Must answer Yes to be eligible)**
1	☐	☐	Subject is ≥ 18 and < 80 years of age.
2	☐	☐	Be a cancer survivor with diagnosis of AIC.
3	☐	☐	Have an LVEF ≤ 45% by cMRI.
4	☐	☐	Be in NYHA class II-III.
5	☐	☐	Have received the initial diagnosis of AIC at least six months earlier and be on stable, optimally tolerated therapy with beta-blockers, ACE inhibitors/ARBs, and/or aldosterone antagonists for 3 months, unless contraindicated.
6	☐	☐	Have a period of at least two years of clinical cancer-free state* and low likelihood of recurrence (a five-year risk of recurrence estimated at 30% or less), as determined by an oncologist, based on tumor type, response to therapy, and negative metastatic work-up at the time of diagnosis. **exceptions to this are carcinoma in situ or fully resected basal and squamous cell cancer of the skin*
7	☐	☐	Be a candidate for cardiac catheterization.
	Y	**N**	**Exclusion Criteria (Must answer No to all questions to be eligible)**
1	☐	☐	A life expectancy <12 months.
2	☐	☐	A CT scan or baseline cardiac MRI showing new tumor or suspicious lymphadenopathy raising concern of malignancy.
3	☐	☐	Presence of obstructive CAD as determined via imaging within 5 years prior to study enrollment provided there have been no symptoms or evidence of CAD since the test (see Section 4.1 for imaging guidance).
4	☐	☐	Had a previous myocardial infarction.
5	☐	☐	A history of radiation therapy AND evidence of constrictive physiology and/or evidence of other patterns of non-ischemic cardiomyopathy on cardiac MRI (e.g. amyloidosis, sarcoidosis, hemochromatosis, pure radiation-induced cardiomyopathy, etc.) not consistent with AIC being the dominant etiology of heart failure.
6	☐	☐	Severe valvular heart disease including mechanical or bioprosthetic heart valve; or 2) severe valvular (any valve) insufficiency/regurgitation within 12 months of consent.
7	☐	☐	Aortic stenosis with valve area ≤ 1.5cm^2.
8	☐	☐	A history of LV reduction surgery or cardiomyoplasty.
9	☐	☐	Evidence of cardiogenic shock.
10	☐	☐	A history of ischemic or hemorrhagic stroke within 90 days of baseline testing.
11	☐	☐	Liver dysfunction during baseline testing, as evidenced by enzymes (e.g., AST, ALT, alkaline phosphatase) greater than 3 times upper limit of normal.
12	☐	☐	Diabetes with poorly controlled blood glucose levels (HbA1c > 8.5%).
13	☐	☐	An underlying autoimmune disorder or current immunosuppressive therapy (e.g., chronic corticosteroid, rheumatologic or immune modulating therapy) or likelihood of use of immunosuppressive therapy during participation in the trial *(medications will be considered on a case by case basis)* .
14	☐	☐	A baseline eGFR < 35 ml/min/1.73m^2.
15	☐	☐	A contrast allergy that cannot adequately be managed by premedication.
16	☐	☐	Received gene or cell-based therapy from any source within the previous 12 months.

FORM NO. SEN023			
Acrostic Identifier:			
Study ID:			
Date source form completed (mm/dd/yyyy): _____/_____/_____			
Eligibility Criteria			
17	☐	☐	A hematologic abnormality during baseline testing as evidenced by hemoglobin < 9 g/dl; hematocrit < 30%; absolute neutrophil count < 2,000 or total WBC count more than 2 times upper limit of normal; or platelet values < 100,000/ul.
18	☐	☐	Evidence of active systemic infection at time of study product delivery.
19	☐	☐	HIV, and/or active HBV or HCV.
20	☐	☐	Coagulopathy (INR > 1.5) not due to a reversible cause (e.g., warfarin and/or Factor Xa inhibitors) (see Section 6.4 re: injection procedure and anticoagulation therapy) *Note: Subjects who cannot be withdrawn from anticoagulation will be excluded.*
21	☐	☐	Presence of LV thrombus *(see guidance in Section 6.6.3)* .
22	☐	☐	Presence of a pacemaker and/or ICD generator with any of the following limitations/conditions: If yes, please check the relevant limitation(s)/condition(s) below (required): ☐ manufactured before the year 2000 ☐ leads implanted < 6 weeks prior to consent ☐ non-transvenous epicardial, or abandoned leads ☐ subcutaneous ICDs ☐ leadless pacemakers ☐ any other condition that, in the judgement of device-trained staff, would deem an MRI contraindicated
23	☐	☐	Pacemaker-dependence with an ICD *(Note: pacemaker-dependent candidates without an ICD are not excluded).*
24	☐	☐	A cardiac resynchronization therapy (CRT) device implanted less than 3 months prior to consent.
25	☐	☐	Other MRI contraindications (e.g. patient body habitus incompatible with MRI).
26	☐	☐	An appropriate ICD firing or anti-tachycardia pacing (ATP) for ventricular fibrillation or ventricular tachycardia within 30 days of consent.
27	☐	☐	Ventricular tachycardia ≥ 20 consecutive beats without an ICD within 3 months of consent, or symptomatic Mobitz II or higher degree atrioventricular block without a functioning pacemaker within 3 months of consent.
28	☐	☐	A history of drug abuse (use of illegal “street” drugs except marijuana, or prescription medications not being used appropriately for a pre-existing medical condition) or alcohol abuse (≥ 5 drinks/day for > 3 months), or documented medical, occupational, or legal problems arising from the use of alcohol or drugs within the past 24 months.
29	☐	☐	Cognitive or language barriers that prohibit obtaining informed consent or any study elements (interpreter permitted).
30	☐	☐	Participation (currently or within the previous 30 days) in a cardiac related investigational therapeutic (including stem cell based therapies) or device trial.
31	☐	☐	Pregnancy, lactation, plans to become pregnant in the next 12 months, or is unwilling to use acceptable forms of birth control during study participation.
32	☐	☐	Any other condition that, in the judgment of the Investigator or Sponsor, would be a contraindication to enrollment, study product administration, or follow-up.
	☐	This subject became ineligible during the screening process; not all data were collected to answer every question; all questions addressed with the patient have been answered.	

FORM NO. SEN023	
Acrostic Identifier:	
Study ID:	
Date source form completed (mm/dd/yyyy): _____/_____/_____	
Eligibility Criteria	
Comments:	
☐ Investigator reviewed Eligibility Criteria worksheet	Date Investigator reviewed (mm/dd/yyyy): ___/___/_____

PI Signature_____ Date: ____/____/_____

RNC Signature_____ Date: ____/____/_____

Entered to eCRF ☐ Initials _____

FORM NO. SEN025		
Acrostic Identifier:		
Study ID:		
Date source form completed (mm/dd/yyyy): _____/_____/_____		

Study Product Injection (SPI)

Vital Signs Pre-Procedure (Pre-Study Product Injection)

Date (mm/dd/yyyy): _____/_____/_____ Time (hhmm): __ __ __ __

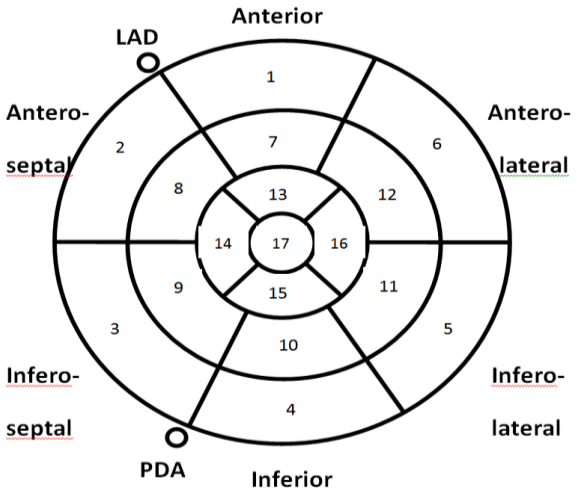
Temperature:	__ __.__°F
Respirations:	__ __ breaths/min
Heart rate:	__ __ __ beats/min
Blood pressure:	__ __ __ / __ __ __ mmHg (supine) SBP DBP

Study Product Injection Period

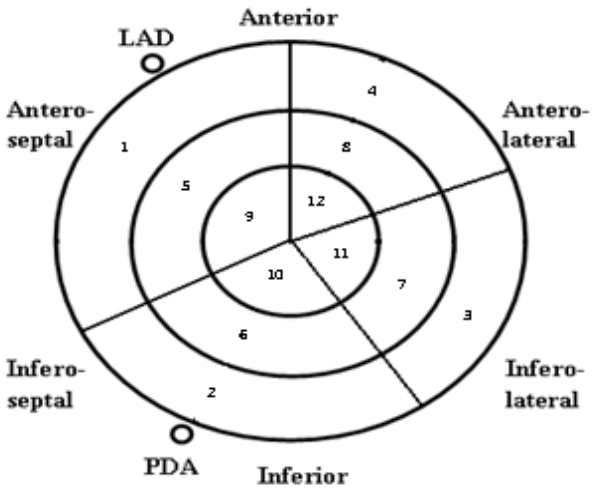
Procedure start date (mm/dd/yyyy): ___/___/___

Catheterization procedure	Start time (hhmm): __ __ __ __	Stop time (hhmm): __ __ __ __
Mapping procedure	Start time (hhmm): __ __ __ __	Stop time (hhmm): __ __ __ __
Injection procedure	Start time (hhmm): __ __ __ __	Stop time (hhmm): __ __ __ __

Diagram of Mapping & Injection Segments



17 segment (TX)



12 segment (all others)

FORM NO. SEN025

Acrostic Identifier:

Study ID:

Date source form completed (mm/dd/yyyy): _____/_____/_____

Injection Information

Injection Points	Segment Number	Loop Stability	UPV	Presence of PVCs	Volume of Injection	Not Done
1		_____ mm	_____mV	Yes ☐ No ☐	_____ ml	☐
2		_____ mm	_____mV	Yes ☐ No ☐	_____ ml	☐
3		_____ mm	_____mV	Yes ☐ No ☐	_____ ml	☐
4		_____ mm	_____mV	Yes ☐ No ☐	_____ ml	☐
5		_____ mm	_____mV	Yes ☐ No ☐	_____ ml	☐
6		_____ mm	_____mV	Yes ☐ No ☐	_____ ml	☐
7		_____ mm	_____mV	Yes ☐ No ☐	_____ ml	☐
8		_____ mm	_____mV	Yes ☐ No ☐	_____ ml	☐
9		_____ mm	_____mV	Yes ☐ No ☐	_____ ml	☐
10		_____ mm	_____mV	Yes ☐ No ☐	_____ ml	☐
11		_____ mm	_____mV	Yes ☐ No ☐	_____ ml	☐
12		_____ mm	_____mV	Yes ☐ No ☐	_____ ml	☐
13		_____ mm	_____mV	Yes ☐ No ☐	_____ ml	☐
14		_____ mm	_____mV	Yes ☐ No ☐	_____ ml	☐
15		_____ mm	_____mV	Yes ☐ No ☐	_____ ml	☐
16		_____ mm	_____mV	Yes ☐ No ☐	_____ ml	☐
17		_____ mm	_____mV	Yes ☐ No ☐	_____ ml	☐
18		_____ mm	_____mV	Yes ☐ No ☐	_____ ml	☐
19		_____ mm	_____mV	Yes ☐ No ☐	_____ ml	☐
20		_____ mm	_____mV	Yes ☐ No ☐	_____ ml	☐

Total Injections: _____ | Total Volume: _____ | *Shaded fields are filled in by SPI eCRF programming*

FORM NO. SEN025			
Acrostic Identifier:			
Study ID:			
Date source form completed (mm/dd/yyyy): _____/_____/_____			
Vital Signs Post-Procedure (Post-Study Product Injection)			
Date (mm/dd/yyyy): _____/_____/_____ Time (hhmm): __ __ __ __			
Temperature:	__ __.__°F		
Respirations:	__ __ breaths/minute		
Heart rate:	__ __ __ beats/minute		
Blood pressure:	__ __ __ / __ __ __ mmHg (supine) SBP DBP		
Questions			
1. Did the patient experience an adverse event during mapping? (If yes, please complete AE form)		Yes ☐	No ☐
2. Were all 20 injections given? (If no, please explain in Comments)		Yes ☐	No ☐
3. Was the injection procedure prematurely stopped due to any reason listed below? (If yes, complete AE and/or UP form)		Yes ☐	No ☐
4. Was the procedure restarted?		Yes ☐	No ☐ N/A ☐
5. Did the patient experience an adverse event during the injection procedure? (If yes, complete AE form)		Yes ☐	No ☐
6. Were concomitant medications given? (If yes, please update Medications form)		Yes ☐	No ☐
Comments:			

Entered to eCRF ☐ Initials _____

FORM NO. SEN025
Acrostic Identifier:
Study ID:
Date source form completed (mm/dd/yyyy): _____/_____/_____

5.5 Circumstances That May Affect Study Product Delivery

If any of the following symptoms occur before or during SPI, they could indicate a serious clinical deterioration. If any of the following events/symptoms occurs, the procedure should be temporarily halted and the patient should be reevaluated for suitability to continue with the treatment under investigation:

1. Hypotensive episode defined as a sustained drop in blood pressure exceeding 20 mmHg not responsive to fluid administration
2. Hemodynamically significant arrhythmia requiring antiarrhythmic therapy
3. Two episodes of sustained ventricular tachycardia/ventricular fibrillation requiring cardioversion
4. Hemodynamically unstable
5. Fever (temperature increase to ≥100.4°F)
6. Cardiac perforation
7. Clinical signs and symptoms indicating a cerebrovascular accident

FORM NO. SEN027				
Acrostic Identifier:				
Study ID:				
Date source form completed: _____/_____/_____				
Follow-Up Telephone Contact				
Date of Call/Contact: _____/_____/_____				
Contact Initiated by (check one):	☐ Site	☐ Subject		
Questions being answered by:	☐ Patient	☐ Family Member	☐ Other	
Vital Status				
a. What is the patient's vital status?	☐ Living	☐ Deceased		
If deceased, provide estimated date:				
If deceased, what is the known cause of death?				
b. Does the patient have an ICD?	☐ Yes	☐ No	☐ Unknown	
If yes, estimate the date last fired?				
c. Is the patient on an assist device?	☐ Yes	☐ No	☐ Unknown	
d. Has the patient had a heart transplant?	☐ Yes	☐ No	☐ Unknown	
Hospitalizations and Diagnoses				
Since the last time we spoke, have you had any of the following?				
a. Heart attack (myocardial infarction)	☐ Yes	☐ No	☐ Unknown	
If yes, provide estimated date:				
b. Bypass surgery (CABG)	☐ Yes	☐ No	☐ Unknown	
If yes, provide estimated date:				
c. Stroke	☐ Yes	☐ No	☐ Unknown	
If yes, provide estimated date:				
d. Other heart procedures (caths, stents, balloons, etc.)	☐ Yes	☐ No	☐ Unknown	
If yes, provide up to 3 procedures and estimated dates:				
1) Describe:	Date:			
2) Describe:	Date:			
3) Describe:	Date:			

FORM NO. SEN027	
Acrostic Identifier:	
Study ID:	
Date source form completed: _____/_____/_____	
Follow-Up Telephone Contact	
e. Any new cancer diagnoses (including skin) ☐ Yes ☐ No ☐ Unknown	
If yes, provide estimated date:	
Indicate type of cancer(s):	
Comments:	
Name of person collecting information:	

Entered to eCRF ☐ Initials _____

FORM NO. SEN077	
Acrostic Identifier:	
Study ID:	

Date source form completed (mm/dd/yyyy): _____/_____/_____

End of Study

Date of final follow-up study visit (mm/dd/yyyy): _____/_____/_____

Reason for discharge from the study:

- ☐ Completed study
- ☐ Withdrawn
- ☐ Lost to follow-up
- ☐ Screen Failure

Date of discharge from study (mm/dd/yyyy): _____/_____/_____

If "Withdrawn", please check the primary reason for withdrawal:

Reasons that require follow-up:

- ☐ Serious Adverse Event (until resolved) Event Number:
- ☐ Pregnancy (1 year post birth) Event Number:
- ☐ Other Describe:

Reasons that DO NOT require follow-up:

- ☐ Death Event Number:
- ☐ Adverse Event Event Number:
- ☐ Withdrawal of consent
- ☐ Protocol Deviation/Violation
- ☐ Investigator Discretion Describe:
- ☐ Sponsor Discretion Describe:
- ☐ Other Describe:

Please verify the following tasks are complete:

☐	All Informed Consents forms are properly signed/dated and available
☐	Hard copy workbooks are signed, dated and present in the CCTRN source document patient binder; workbooks may be grouped by a visit with one signature per visit
☐	All source document data have been entered into the electronic CRF database
☐	All electronic CRFs have been submitted to the DCC
☐	I have reviewed all case report forms for this patient and found them to be in complete agreement with the source documents
☐	If any questions arise from the DCC data review (due to missing, unclear, or incorrect entries), the authorized staff will supply appropriate corrections

Comments:

PI Signature _____ Date: _____/_____/_____

RNC Signature _____ Date: _____/_____/_____

Entered to eCRF ☐ Initials _____