

INSTRUCTIONS: Complete for each patient with known or suspected dilated cardiomyopathy who is scheduled for a clinical echocardiogram. The form should be completed on the date of the echocardiogram.

Definition of dilated cardiomyopathy: Dilated cardiomyopathy (also referred to as congestive cardiomyopathy) is a disease of the heart muscle characterized by dilatation and impaired contraction of the left or both ventricles.

Section A: KEY IDENTIFYING INFORMATION

- A1. Study Identification Number _____ - _____ - _____ - _____ - _____ - _____ - _____ - _____ - _____ - _____ **REMOVED**
BLIND_ID
BLIND_SITE
- A2. Date of eligibility screening _____ / _____ / _____ - _____ - _____ - _____ - _____ **REMOVED**
M M / D D / Y Y Y Y **AGE_SCREEN**
- A3. Date of echocardiogram _____ / _____ / _____ - _____ - _____ - _____ - _____ **REMOVED**
M M / D D / Y Y Y Y **AGE_IECHO**
- A4. Date of form completion _____ / _____ / _____ - _____ - _____ - _____ - _____ **REMOVED**
M M / D D / Y Y Y Y **AGE_COMP**
- A5. Name of person completing form _____ **REMOVED**
PRINT FULL NAME INITIALS

Section B: PATIENT INFORMATION

- B1. Date of birth _____ / _____ / _____ - _____ - _____ - _____ - _____ **REMOVED**
M M / D D / Y Y Y Y
- B2. Gender **GENDER** MALE 1 FEMALE 2
- B3. Race **RACE** WHITE 1
 BLACK OR AFRICAN AMERICAN 2
 ASIAN 3
 AMERICAN INDIAN OR ALASKAN NATIVE 4
 NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER 5
 MORE THAN ONE RACE 6
 a. Specify _____ **REMOVED**
 OTHER 99
 b. Specify _____ **REMOVED**
 UNKNOWN -8
- B4. Is patient of Hispanic or Latino origin? **HISPANIC** YES 1 NO 2 UNKNOWN -8

Section C: INCLUSION CRITERIA FOR BASELINE ECHOCARDIOGRAM

		YES	NO
C1.	Age < 22 years AGELT22	1	2
C2.	Diagnosis of known or suspected dilated cardiomyopathy DIAGNOS	1	2
C3.	Disease onset > 2 months prior to baseline echocardiogram ONSETGT2	1	2
C4.	Expected to have a repeat echocardiogram at a PHN site ≥ 3 months and < 13 months after the baseline echocardiogram EXPECHO	1	2

Section D: EXCLUSION CRITERIA FOR BASELINE ECHOCARDIOGRAM

D1.	Suspected acute myocarditis ACUTEMYO	1	2
D2.	Hypertrophic cardiomyopathy IHOCM [Definition: Cardiomyopathy characterized by left and/or right ventricular hypertrophy, which is usually asymmetric and involves the interventricular septum, without underlying hemodynamic cause. Left ventricular cavity size is usually not increased and systolic function is usually normal.]	1	2
D3.	Restrictive cardiomyopathy IRESTCM [Definition: Restrictive cardiomyopathies (also referred to as obliterative cardiomyopathies) are marked by diastolic dysfunction. The left ventricle is usually normal sized or small. Systolic function is usually preserved. Marked hypertrophy is absent, although mild thickening may be observed.]	1	2
D4.	Tachycardia-induced cardiomyopathy ITACHYCM [Definition: Ventricular dysfunction secondary to documented chronic supraventricular or ventricular tachycardia]	1	2
D5.			
D6.	Congenital heart disease (repaired or unrepaired) CHD	1	2
D7.	Ventricular paced rhythm IPACED	1	2
D8.	Atrial or ventricular ectopy at ratio greater than 1:4 IECTOPY	1	2
D9.	Currently on intravenous inotropic support INOTROPE	1	2
D10.	Current left ventricular assist device (LVAD) or extracorporeal membrane oxygenation (ECMO) LVADECMO	1	2
D11.	Heart transplant waiting list status of 1A or 1B for US <u>or</u> 3, 3.5, or 4 for Canada TRAN1A1B	1	2

Section D: EXCLUSION CRITERIA FOR BASELINE ECHOCARDIOGRAM (continued)

		YES	NO
D12.	Co-morbid condition that precludes the ability to successfully obtain an echocardiogram according to the specifications of the study protocol COMORBID	1	2

Patient is **not eligible** for a study echocardiogram if any answer is in a shaded area, i.e., if any of C1-C4=NO or any of D1-D12=YES

Section E: DETERMINATION OF ELIGIBILITY PRIOR TO PERFORMANCE OF BASELINE ECHOCARDIOGRAM

E1. Is patient eligible for a study echocardiogram? **ECHOELIG**
 YES 1 NO 2 (END)

Section F: PATIENT CONSENT

F1. Is the patient old enough to consent to study participation without informed consent by a parent or legal guardian? **PTADULT**
 YES 1
 NO 2 (F2)

a. Did the patient sign the informed consent document? **PTCONS**
 YES 1 (END)
 NO 2 (END)

F2. Did the patient's parent or legal guardian sign the informed consent document? **PRNTCONS**
 YES 1
 NO 2 (END)

a. Did the patient sign the age-appropriate assent or consent document? **PTASSENT**
 YES 1
 NO 2
 NOT APPLICABLE - 1

If [F1a=YES or F2=YES] and F2a=YES or NOT APPLICABLE, complete study echocardiogram and Forms V101W and V101

<Created variable> Consent to VVV study? **CONSENT:**