ECHOCARDIOGRAPHY
MANUAL OF OPERATION (MOO)
FOR THE HEART FAILURE NETWORK

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CONTENTS

A. ECHOCARDIOGRAPHY FOR HFN TRIALS ........................................3
   1. INTRODUCTION ........................................................................3
   2. HFN ECHO PROTOCOL ..........................................................3
   3. IMAGE ACQUISITION ..............................................................4
   4. MEASUREMENTS .................................................................7
   5. DATA ANALYSIS .................................................................19

B. QUALITY CONTROL / CERTIFICATION OF ECHO LAB ................19
   1. QUALITY CONTROL OF CLINICAL CENTERS ......................19
   2. TRAINING SESSIONS ............................................................20
   3. REQUIREMENT FOR CERTIFICATION .................................20
   4. DATA TRANSFER ...............................................................20
   5. QUALITY CONTROL OF THE ECHO CORE LAB PERSONNEL ....20

C. ECHO CORE LAB PERSONNEL AND CONTACT ..........................21
   1. DIRECTOR ...........................................................................21
   2. COORDINATOR .................................................................21
   3. PHYSICIAN READERS ........................................................21
   4. SONOGRAPHERS ...............................................................21
   5. SECRETARY .........................................................................21

D. APPENDIX ................................................................................22
   1. ECHO IMAGE CHECKLIST (APPENDIX 1) .........................22
   2. ECHO CORE LAB SHIPMENT FORM (APPENDIX 2) ..........24
   3. INSTRUCTIONS FOR SHIPMENT FORM (APPENDIX 3) ....25
   4. PATIENT INFORMATION FORMS (APPENDIX 4) ................26
   5. INSTRUCTIONS FOR PATIENT INFORMATION FORM (APPENDIX 5) .28
   6. ECHO CORE LAB CERTIFICATION FORM (APPENDIX 6) ....30
   7. INSTRUCTIONS FOR CERTIFICATION FORM (APPENDIX 7) ....31

E. MISCELLANEOUS INFORMATION ..............................................33
   1. PROCESS FLOWS FOR STUDY ECHOES ..........................33
   2. REQUIREMENTS ...............................................................33
   3. EXAMPLES OF TECHNICAL PROBLEMS WITH ECHO RECORDINGS ....34
   4. FREQUENTLY ASKED QUESTIONS AND TECHNICAL TIPS ....34
   5. QUESTIONS? ......................................................................35
A. ECHOCARDIOGRAPHY FOR HFN TRIALS

1. INTRODUCTION

The primary aim of the Heart Failure Clinical Research Network (HFN) is to investigate new therapies or novel uses for existing therapeutic options for patients with heart failure. Over a three year period, eight clinical trials of pharmaceutical as well as surgical treatment options will be conducted at nine clinical centers. Echocardiography will be required to identify potential patients to enrollment but also to determine and/or to monitor response to therapy. The purpose of the Echocardiography Core Laboratory is to support the clinical trials through standardization of image acquisition and measurements, certification of clinical sites, determination of the quality of studies performed at these sites, quality assurance of the study personnel (sonographers and physician echocardiographers) involved in image acquisition and interpretation at the clinical sites, transfer of echocardiography studies to Echo Core Lab, and transfer of echocardiographic data to the Data Management Center.

The Manual of Operations (MOO) for the HFN will describe standardized techniques for measurement and assessment of left ventricular ejection fraction (LVEF), LV diastolic function, LV volumes, LV geometry, right ventricular function, as well multiple hemodynamic variables. The specific timing and frequency of baseline and serial echocardiography for each trial has been described previously in the protocol for each individual trial. The noninvasive hemodynamic and functional variables measured echocardiographically will be analyzed to determine parameters clinically helpful for selecting a treatment modality and for assessing prognosis in patients with heart failure.

2. HFN ECHO PROTOCOL

Although the frequency, timing, and focus of echocardiography for the HFN trials will vary according to the specific protocol, a single, standardized, HFN echocardiographic protocol will be applied to all studies. This standardized echocardiography protocol is mostly similar to clinically performed examination. This protocol will include standard echocardiographic measurements of left ventricular size, geometry, mass, systolic and diastolic function, right ventricular function, estimation of right ventricular systolic pressure, qualitative analysis of tricuspid and aortic regurgitation, and quantitative and qualitative analysis of mitral regurgitation.

HFN ECHO DATA TO BE OBTAINED AND MEASURED

1. Left ventricular (LV) ejection fraction, systolic function, mass, and volumes (Simpson’s biplane)
   a. LV end-diastolic and end-systolic dimensions
   b. LV end-diastolic and end-systolic volumes
   c. LV stroke volume estimate
2. LV sphericity
   a. LV maximum short axis dimension
   b. LV long axis dimension
3. LV diastolic function and LV filling pressure estimate
   a. Mitral inflow pulsed wave Doppler (E wave, A wave, deceleration times at leaflet tips)
   b. Mitral annulus tissue Doppler velocity from lateral and medial mitral annulus
   c. Pulmonary vein pulsed wave Doppler velocities
   d. Diastolic elastance (calculated from (E/E’) / SV)
4. Right ventricular (RV) systolic function
a. RV views  
b. Tricuspid annulus tissue Doppler velocity from RV lateral annulus  
c. Tricuspid annular plane systolic excursion (optional)  
5. Left atrial (LA) volumes  
6. Pulmonary artery systolic pressure estimate  
   a. Tricuspid regurgitation peak continuous wave Doppler velocity  
   b. Right atrial (RA) pressure estimate from inferior vena cava size  
7. Aortic regurgitation (AR) severity  
   a. Color flow imaging  
8. Mitral regurgitation (MR) severity  
   a. Color flow imaging  
   b. Measurement of MR jet area in the LA  
   c. MR vena contracta  
   d. Pulmonary vein pulsed wave Doppler velocities  
   e. Peak early mitral inflow (E wave) pulsed wave Doppler velocity  
   f. Proximal isovelocity surface area (PISA)  
   g. MR jet continuous wave Doppler velocity and TVI  
9. Tricuspid regurgitation (TR) severity  
   a. Color flow imaging  
   b. Measurement of TR jet area in the RA  
10. Ascending aorta measurements  
    a. Sinus of Valsalva level  
    b. Sino-tubular junction level  
    c. Mid ascending aorta level  

**HFN Echo Image Checklist (Appendix 1)**  
- Required images to obtain the measurements described in the HFN Echo Imaging Protocol are detailed in the Image Checklist (Appendix 1).  

**Frequency of Serial Echocardiographic Studies**  
- The SMMART-HF study  
  o Baseline, 6, 12, and 18 months  
- The RELAX study  
  o Baseline and 6 months (24 weeks)  

**3. Image Acquisition and Technique**  
Echocardiographic examination begins with real-time 2D echocardiography which produces high-resolution images of cardiac structures and their movements. These images are usually obtained from four standard transducer locations: parasternal, apical, subcostal, and suprasternal (Fig. 1) by manually rotating and angulating the transducer.
Figure 1. Four transducer positions. 1. Parasternal view. 2. Apical view. 3. Subcostal view. 4. Suprasternal view.

Qualitative and quantitative measurements of cardiac dimensions, area, and volume are derived from 2D images or 2D-derived M-mode recordings. Also, 2D echocardiography provides the framework for Doppler examination and color flow imaging. Newer matrix transducers with more than 2,000 elements allow 3D or multidimensional image of the heart and this may be utilized for a subset of patients for volumetric measurements.

An M-mode (Motion-mode) recording is derived from the parasternal view (transducer position #1) of 2D tomographic images and graphically represents the motion of cardiac structures. It is used primarily to measure cardiac chamber size and timing of cardiac events and to display subtle abnormalities of cardiac motion. Measurement of cardiac dimensions from M-mode echocardiography has been well standardized (See below). For these measurements, a M-mode cursor is drawn as a straight line from the transducer position in any direction in the sector to record the movement of the cardiac structure of interest. However, this traditional method of M-mode may overestimate the dimensions of the structure if the direction of the ultrasound beam is oblique to that structure.

2-D AND DOPPLER ECHOCARDIOGRAPHIC EXAMINATION

ECHOCARDIOGRAPHIC VIEWS

Comprehensive echocardiographic examination requires the following tomographic views. It is recommended to record in the sequence as listed

1. Parasternal long axis view
2. Parasternal short axis view
3. Apical four chamber view
4. Apical long axis view
5. Apical two chamber view
6. Subcostal long axis view
7. Subcostal short axis view
8. Suprasternal notch view (Optional)

ECHO DATA TO BE OBTAINED FROM EACH VIEW
1. Parasternal long axis view
   - LV outflow tract diameter for calculation of stroke volume
   - LV dimensions, short axis dimension
   - LV wall thickness
   - Mitral valve structure/regurgitation
   - Wall motion analysis
   - Left atrial size
   - Aortic valve structure/regurgitation

2. Parasternal short axis view
   - Basal level
   - Papillary muscle level
   - Apical level
   - M-mode of LV at papillary muscle level
   - LV dimensions

3. Apical four chamber view
   - LV dimensions, long axis dimension
   - LV volume for single plane and biplane volumes
   - Mitral regurgitation (color and continuous wave Doppler)
   - Tricuspid regurgitation (color Doppler)
   - LA size and volume
   - Wall motion analysis
   - Tricuspid regurgitation velocity (continuous wave Doppler)
   - Mitral inflow velocity at leaflet tips
   - Mitral inflow velocity at mitral annulus
   - Tissue Doppler of mitral medial and lateral annulus velocity
   - Tissue Doppler recording of tricuspid annulus velocity
   - Pulmonary vein velocities

4. Apical long axis view
   - LV outflow tract velocity and TVI
   - Wall motion analysis
   - Mitral regurgitation
   - Aortic regurgitation (color and continuous wave Doppler) if present
   - Aortic stenosis (continuous wave Doppler) if present

5. Apical two chamber view
   - LV volume for biplane volumes
   - Wall motion analysis
   - Mitral regurgitation
   - LA size and volume

6. Sub-costal views
   - Inferior vena cava
   - Hepatic vein

7. Suprasternal notch view (Optional)
   - Aortic Arch
   - Pulmonary Artery
   - Descending thoracic aorta
3. MEASUREMENTS

PARASTERNAL WINDOWS

LV outflow tract diameter
LV outflow tract diameter (D) is used for calculating stroke volume (SV) and cardiac output (CO) and is measured from the parasternal long axis view (preferably zoomed).

\[
SV = D^2 \times 0.785 \times \text{LVOT TVI}
\]

\[
CO = SV \times \text{Heart Rate}
\]

A 10 second capture of the zoomed or RES views of the LV outflow tract is recommended. To measure the LVOT diameter, a line should be drawn from the junction of the anterior aortic cusp and the ventricular septum to the junction of posterior aortic cusps and the anterior mitral leaflet, perpendicular to the anterior aortic wall.

Figure 2. Parasternal long axis views of LV outflow tract (LVOT) to calculate stroke volume.

LV dimensions and sphericity
- 2-D images of parasternal short axis view will be used to obtain an M-mode of the LV at mid-papillary muscle level for measurement of LV dimensions and wall thickness.
- LV end diastolic and systolic dimensions and wall thicknesses will also be measured from the 2D parasternal long axis view, at the papillary muscle and chordae junction, perpendicular to the long axis of the LV.
- LV sphericity will be calculated as the ratio of the LV long-axis dimension (apical 4 chamber view) and the maximum short-axis dimension (parasternal long axis view).
**Figure 3.** Left ventricular dimensions measured from parasternal long axis and short axis views. Examples of fundamental compared with harmonic imaging.

**LV wall motion analysis (optional)**

LV wall motion analysis will be performed from parasternal and apical views. Harmonic imaging is recommended to improve LV endocardial border definition (see figure 3) and regional wall motion analysis should be performed using the 16 segment model as recommended by the American Society of Echocardiography. A wall motion score will be assigned to each segment depending on its contractility:

1 = normal wall motion,
2 = hypokinesis
3 = akinesis
4 = dyskinesis,
5 = aneurysm, and
9 = not seen.
Figure 4. Regional wall motion analysis using 16 segment model from apical (1, 2, 3) and parasternal short axis (4, 5, 6) views.

LAD segments include:
- Anterior wall at base, mid, and apical level (Segments 2, 8, and 14).
- Anteroseptum at base, mid, and apical level (Segments 1, 7, and 13).
- Lateral and inferior apex (Segments 15 and 16).

The wall motion score index is calculated as the average of the individual wall motion scores of each visualized segment. If more than 2 segments are not visualized, wall motion analysis will not be performed.
Evaluation of mitral regurgitation
The parasternal long axis view and apical views will be used to evaluate the mechanism and the severity of MR. The mitral valve tenting area and also the extent of apical displacement of the posterior mitral leaflet will be measured from the parasternal long axis view. (Figure 5) Severity of mitral regurgitation will be assessed using color flow imaging from parasternal long axis view and apical views. From the apical four or two chamber view, the MR effective regurgitant orifice (ERO) and regurgitant volume (RV) can be calculated using the volumetric or the PISA equation. MR vena contract width should be measured from parasternal long and/or apical long axis view.

Figure 5. Parasternal long axis view showing increased tenting area in a patient with dilated cardiomyopathy (left) and color flow imaging of severe mitral regurgitation (MR) in another patient (right). The narrowest neck of the MR jet is vena contracta.

APICAL WINDOWS

LV from apical views dimension and volume from the apical views
The sphericity index is calculated from the LV long axis dimension and maximal short axis dimension. It is important not to foreshorten the long axis dimension of the LV; the long axis dimensions from the four and two chamber views should be similar (within +/- 10%).

Apical views will be also used to obtain LV volumes using the modified biplane Simpson’s disc method, from a combination of the apical 4 and 2 chamber views. An apical four chamber single plane volume should also be measured. The LV endocardial border will be traced contiguously from one side of the mitral annulus to the other side excluding the papillary muscles and trabeculations. The reliability of LV dimension and volume measurements is dependent on the quality of the LV endocardial border definition, and therefore an intravenous contrast agent should be used to enhance the endocardial border definition whenever feasible.

LVEF will be determined from LV volumes using the following formula.

\[
LVEF = \frac{(EDV-ESV)}{EDV}
\]

where EDV = end-diastolic volume and ESV = end-systolic volume.

If the definition of the LV endocardial border is not satisfactory for digitization, LVEF will be determined visually. If arrhythmia prevents quantitative measurements, LVEF will be estimated visually. Please record at least 5 cardiac cycles (digital) or 10 seconds (videotape) of each apical view. All apical views should be acquired at the same imaging depth.
Figure 6. Biplane left ventricular volume measurement using apical 4 and 2 chamber. It is important not to foreshorten the apical segment. Long axis dimensions should be similar between apical 4 and 2 chamber views.

Left atrial size (volumes)
When tracing the left atrial areas, care should be taken to exclude the pulmonary vein from the left atrial trace. The posterior wall of the atrium should be carefully defined to ensure an accurate trace of the left atrium in the two chamber view. Left atrial volume can be determined from two orthogonal views of the left atrium (apical four and two chamber views, figure 7). Left atrial volume is then calculated by the area length method and indexed to body surface area:

\[
\text{Left atrial volume} = \frac{(0.85 \times \text{Area}_{4ch} \times \text{Area}_{2ch})}{\text{Length}}
\]

The area of the left atrium is traced in both the apical four and two chamber views and the length of the atria are measured in both views and the shortest length is used in the calculation.
Figure 7. Apical four (A4C) and two chamber (A2C) views for LA area measurements which are in turn used to calculate LA volume.

**Mitral inflow velocity for diastolic function and filling pressure assessment**

Mitral inflow velocity will be used for assessment of diastolic filling pattern. The E velocity (peak early filling), A velocity (peak late filling), and deceleration time of E velocity will be measured. A small sample volume (1 to 2 mm) should be placed at the tip of the mitral leaflet during diastole. The direction of the ultrasound beam should be parallel with the jet of the mitral inflow direction which is usually directed laterally especially when the left ventricle is dilated. In these cases transducer position should be shifted laterally when mitral inflow velocity is required (see figure 8).

The filter should be lowered to record and show low velocities and at least 20 cardiac cycles of the mitral inflow signal should be recorded. Examples of mitral inflow Doppler recordings of mild diastolic dysfunction with delayed myocardial relaxation (left), normal (center), and advanced restrictive filling (right) pattern with respective E velocity, A velocity, E/A ratio, and deceleration time (DT) measurements are shown.
Figure 9. Recordings of mitral inflow velocities of mild diastolic dysfunction with abnormal relaxation (left), normal or pseudo-normal (middle), and severe diastolic dysfunction with restrictive filling and increased filling pressure (right).

Tissue Doppler of mitral and tricuspid annulus velocity
This is a simple recording of the mitral annulus velocity using pulsed wave Doppler. Usually, preset or program option should be selected for obtaining tissue Doppler (DTI function after selecting preset, or program function), and then a sample volume should be placed both at the septal and lateral portion of the mitral annulus to record the E’ and A’ velocity of the mitral annulus. Another recording should be done with the sample volume at the lateral tricuspid annulus.

Figure 10. Sample volume placed at the mitral annulus for recording of DTI (left). Examples of normal and abnormal relaxation patterns (right).

Color coded -tissue velocity for Strain imaging (Optional)
If recording of color-coded tissue velocity imaging is feasible, 3 apical views (4 chamber, long axis, and 2 chamber) should be obtained for strain analysis. Preferably, image of the entire LV should be displayed in each view. Another way to obtain strain is 2-D speckle tracking echocardiography of 3 apical views and 3 parasternal short axis views. These raw data (not DICOM) from these images need to be stored as digital images onto a CD.
Figure 11. Example of color coded tissue Doppler imaging of apical four chamber view with the left ventricle on the left side (left) and 2-D speckle tracking strain imaging for cardiac torsion (right).

**Pulmonary vein velocity**
Pulmonary vein flow velocities are best obtained from the apical four chamber view by placing a 3-5 mm size sample volume in the pulmonary vein. In patients with difficult apical views, color flow imaging may be helpful to identify pulmonary vein flow. It is usually best to use the right lower pulmonary vein draining into the left atrium right next to the atrial septum.

Figure 12. Apical four chamber view (left) with color flow imaging of pulmonary vein (arrow). Pulsed wave Doppler recording (right) with systolic (S), diastolic (D), and atrial flow reversal (A).

**Mitral inflow propagation velocity (Optional):**
Propagation velocity is obtained by color M-mode of the mitral inflow. From an apical view, color flow imaging is used to demonstrate mitral inflow. A cursor should be placed along the center of the mitral inflow color jet, and the color baseline shifted upward until just the center of the jet becomes blue. An M-mode of the color flow is then obtained as shown (figure 12).
Mitral inflow propagation velocity in a normal patient. Color M-mode of the mitral inflow is shown (right upper panel).

**LVOT velocity and time velocity integral**

These measurements will be used to calculate the stroke volume and MR volume if present. A small sample volume should be placed near the aortic annulus using the apical long axis view. A nice, laminar flow should be recorded and the outer portion of the LV outflow tract velocity will be traced to obtain time velocity integral (TVI). At least 5-10 cycles are required. Figure 14 shows laminar LVOT velocity (black in the center) obtained from the apical long axis view. Time velocity can be measured by tracing the outer boundary of the velocity, not modal velocity.

**Figure 13.** Mitral inflow propagation velocity

**Figure 14.** LVOT velocity

**Quantitation of Mitral Regurgitation**

*Volumetric method:* The mitral regurgitant volume is equal to the difference between the SV across the LV outflow tract and the SV across mitral annulus, assuming there is no aortic regurgitation.

\[
MR \text{ volume} = \text{Mitral Inflow } SV - \text{LVOT } SV
\]
SV is calculated as the product of area and TVI of flow velocity across a fixed orifice. The area of the mitral valve annulus is calculated from the apical four-chamber view during diastole, and mitral valve TVI is obtained from the apical four-chamber view placing a small (2 mm or less) sample volume at the center of the mitral annulus. The SV across the MV is then calculated:

\[ \text{Mitral Inflow SV} = D^2 \times \text{mitral valve} \times 0.785 \times \text{TVI mitral inflow} \]

SV across the LVOT is calculated as described previously.

**PISA method:** Using color flow imaging, the most optimal view of MR should be defined. With the region of interest centered on the regurgitant orifice, a zoomed image of the regurgitant jet at the orifice with color flow should be obtained. The zero baseline of the color map should then be shifted downward (an aliasing velocity of 25-40 cm/s is recommended) to increase the radius of the PISA, shown as an orange-yellow hemisphere, proximal to the regurgitant orifice (figure 14). The negative aliasing velocity is equal to the velocity at the surface of PISA. Record at least 20 seconds of this view to demonstrate a PISA immediately proximal to the MR jet in the LV and measure the PISA radius (r) at mid-systole. A continuous wave Doppler recording of MR to obtain the time velocity integral (TVI) and peak velocity should also be obtained. MR quantification by the PISA method is then calculated as below:

\[ ERO = \frac{6.28 \times \text{radius}^2 \times \text{aliasing velocity}}{\text{Peak MR velocity}} \]

\[ \text{Regurgitant volume} = ERO \times \text{MR TVI} \]

**Summary of PISA method:**
1. Identify MR by color flow imaging
2. Shift color baseline downwards to an aliasing velocity of 25-40 cm/s and notice PISA in yellow-orange hemisphere shape
3. Zoom or RES the region of interest
4. Cine-loop to measure PISA radius at mid-systole
5. Record MR velocity by CW
6. Measure peak velocity and TVI of MR in cm/s and cm, respectively
Figure 15. Quantitation of mitral regurgitation by PISA method. Manipulation of the baseline of the color map will produce the PISA hemisphere (lower left). Continuous wave Doppler measurement of the mitral regurgitant tissue velocity integral and peak velocity are also required (lower middle and right).

_Vena Contracta_: This will be measured from the narrowest width of MR jet immediately below the mitral regurgitant orifice in the left atrium in either the parasternal long axis or apical views. A zoom or RES view of the vena contracta (VC) is recommended (figure 16).

![Vena Contracta of the mitral regurgitant jet.](image)

Figure 16. Vena contracta of the mitral regurgitant jet.

**Tricuspid regurgitation velocity**
Tricuspid regurgitation velocity (continuous wave Doppler) can be obtained by the duplex imaging probe or non-imaging probe from the right ventricular inflow view, apical four chamber view, or parasternal short axis view at the basal level or even the subcostal view. Since there is a respiratory variation in tricuspid regurgitation velocity, the velocity should be recorded at end – expiration. When there is a significant variation, the highest velocity should be used.
Pulmonary artery systolic pressure: Systolic PAP will be estimated from the peak tricuspid regurgitation (TR) velocity obtained with continuous wave Doppler echocardiography. It is usually obtained from the right ventricular inflow view, parasternal short-axis view or, most frequently, the apical view. After peak TR velocity is measured, systolic PA pressure is calculated as the following:

\[ \text{Systolic PAP} = 4 \times \text{TR velocity}^2 + \text{right atrial pressure (RAP)}. \]

RAP is estimated from the inferior vena cava (IVC) caliber response to inspiration. If the IVC dimension decreases 40% or greater with inspiration, RAP is assessed to be 5 mm Hg. If IVC caliber decreases 10-39% with inspiration, RAP is estimated to be 10 mm Hg. If the IVC dimension decreases less than 10%, RAP is assumed to be 15 mm Hg. If the TR velocity signal is weak or not adequate, intravenous administration of Definity (0.2 - 0.3 cc followed by saline flush) will improve the signal.

RV size and systolic function assessment (optional)
RV size will be measured as shown below. RV systolic function will be visually assessed as “normal”, “mild-moderate dysfunction”, or “severe dysfunction.” Tricuspid lateral annulus velocity (see Tissue Doppler section) will also be used to assess RV systolic function. Tricuspid annular plane systolic excursion (TAPSE) can also be obtained by placing an M-mode cursor through the tricuspid lateral annulus in the apical four chamber view. TAPSE is measured from the maximal ascent of the annulus to the maximal descent in ventricular systole.
DATA ANALYSIS

Digital images from echocardiograms performed at participating clinical centers should be uploaded on to the HEART IT server. For echocardiograms in the form of videotape or CD, the necessary echocardiographic images and Doppler recordings will be digitized by a research sonographer using the Digiview workstation. The captured digital data will be used for quantitative data analysis and stored in an optical disk or a jukebox. Analysis will be performed initially by a research sonographer and approved by a Core Lab cardiologist. If there is a discrepancy, a second Core Lab cardiologist will review the image to resolve the discrepancy.

All measurements and analyses will be performed without knowledge of other clinical or laboratory data. An average of 1-3 cycles will be used for sinus rhythm and of 3-5 cardiac cycles for atrial fibrillation. In atrial fibrillation or in frequent ectopic rhythms, only cardiac cycles with an adequate R-R interval will be used.

B. QUALITY CONTROL

1. QUALITY CONTROL OF CLINICAL CENTERS
To maintain the quality of echocardiographic examinations for the HFN trials, the following steps will be taken:

- Distribution of a MOO and CD demonstrating optimal views and techniques via the HFN website.
- Pretrial review of echocardiograms of one or more patients from each clinical center demonstrating satisfactory acquisition of required images. Echocardiograms will be critiqued to standardize the echocardiographic technique for the each trial.
- Continuous evaluation of echocardiographic quality and techniques to improve subsequent examinations.

The “HFN Echocardiography Manual of Operation” produced by the Echo Core Laboratory will serve as a reference for the required echocardiographic measurements for the HFN trials. Satisfactory acquisition of data by the clinical centers is essential to obtain reliable
echocardiographic data for the HFN trials. Each clinical site is encouraged to identify a core group
of sonographers who will be responsible for acquiring echocardiographic studies for the HFN
trials. Limiting data acquisition to this core group will minimize variability and promote and
ensure standardization of image acquisition. A lead sonographer should also be identified to serve
as a liaison with the Echo Core Laboratory.

2. TRAINING SESSION
Even the most complete manual and visual aids are not as effective as a live training session.
Sonographers and echocardiographers from the participating clinical centers are encouraged to
visit the Echo Core Lab located in Rochester, MN for more individualized training, especially for
quantitative echocardiographic measurements. In addition, the Mayo Clinic Echocardiography
Laboratory holds several echocardiography symposia annually. Training can also be done at
Investigators’ meeting and at national meetings including the ACC, AHA, and ASE annual
meetings. Site training at clinical sites will not be offered unless supported by an individual
clinical site or by the HFN.

3. REQUIREMENTS FOR CERTIFICATION
The Echo Laboratory at each clinical site will need to be certified prior to the enrollment of the
first patient in the HFN Trial. For certification, each center is required at minimum to send one or
more studies with the following information;
1) ECG recording on each study
2) Satisfactory view for evaluation of LV volume and EF
3) Satisfactory data acquisition for stroke volume calculation
4) Quantitative assessment of MR (color flow, volumetric method, and PISA)
5) Mitral inflow velocity for diastolic function assessment
Specific instructions for required images and submission of a pre-trial certification echo are
described in the section “Instructions for Certification Form” (see Appendix 7). Subsequent
measurements may be required for certification if further echocardiographic data are requested by
other trials in the HFN.

4. DATA TRANSFER
Echocardiographic images can be recorded either on videotape or digitally stored on CDs at each
of the participating clinical centers. Digital images can be uploaded directly to the HEART IT
server by the clinical sites and accessed by the Echo Core Laboratory personnel. Each site will be
assigned a login and password to upload the digital images to the website. A separate HEART IT
Manual of Operations will be provided.

If unable to upload to HEART IT server, studies can be mailed directly to the Echo Core
Laboratory. Unless otherwise specified, the videotape or CD will not be returned to the clinical
centers.

The shipment and patient information forms are included in the appendix of this MOO,
along with detailed instructions to fill in the forms. These forms should be faxed to the Echo Core
Laboratory with each study echo. If mailing a videotape or CD, copies of the shipment and patient
information forms should also be enclosed with the videotape or CD.

5. QUALITY CONTROL OF THE ECHO CORE LAB PERSONNEL
To minimize intraobserver variability in the analysis of echocardiographic data, all
sonographers and echocardiographers in the Echo Core Laboratory involved in analysis of the
HFN echocardiograms have analyzed or will analyze 20 preselected echocardiography study to
ensure standardization of measurement techniques. To determine interobserver measurement
variability, quality assurance will be performed on every 20th patient.
C. MAYO ECHO CORE LAB PERSONNEL AND CONTACT INFORMATION

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D. APPENDIX

1. Echo Image Checklist (Appendix 1)
2. Echo Core Laboratory Shipment Form (Appendix 2)
3. Instructions for Shipment Forms (Appendix 3)
4. Patient Information Forms (Appendix 4)
5. Instructions for Patient Information Forms (Appendix 5)
6. Echo Core Lab Certification Form (Appendix 6)
7. Instructions for Certification Form (Appendix 7)
APPENDIX 1

ECHO IMAGE CHECKLIST

FOR CINE LOOPS: 5 BEAT CLIPS (IF DIGITAL) OR 10 SECOND CLIPS (IF VIDEOTAPE)
FOR DOPPLER, HIGH SWEEP SPEEDS, CLIP AT LEAST 5 SPECTRAL TRACES IF SINUS RHYTHM, 10 SPECTRAL TRACES IF ATRIAL FIBRILLATION

Attach ECG electrodes from the ultrasound machine to patient being certain an adequate signal is obtained. The ECG will be used for timing of echo measurements by the Echo Core Lab. Most echo values will not be measured on studies with poor quality ECG or those without an ECG.

1. PARASTERNAL WINDOWS
   A. LONG AXIS
      - LV
      - LV WITH COLOR FLOW IMAGING OF MITRAL AND AORTIC VALVE
      - ZOOM VIEW OF MITRAL VALVE (NO COLOR)
      - ZOOM VIEW OF MITRAL VALVE WITH COLOR FLOW IMAGING
      - ZOOM ON LVOT INCLUDING AORTIC VALVE, SINUS OF VALSALVA, AND SINO-TUBULAR JUNCTION
      - ZOOM ON AORTIC VALVE WITH COLOR FLOW IMAGING
      - HIGH PARASTERNAL VIEW OF MID-ASCENDING AORTA
   B. RV INFLOW
      - RV INFLOW
      - RV INFLOW WITH COLOR FLOW IMAGING ON TRICUSPID VALVE
      - CW DOPPLER OF TR VELOCITY
   C. SHORT AXIS AT AORTIC VALVE LEVEL
      - AORTIC VALVE LEVEL INCLUDING RV OUTFLOW TRACT AND TRICUSPID VALVE
      - AORTIC VALVE LEVEL WITH COLOR FLOW IMAGING ON TRICUSPID VALVE
      - CW DOPPLER OF PULMONARY VALVE VELOCITY
      - CW DOPPLER OF TR VELOCITY
      - ZOOM VIEW OF AORTIC VALVE
      - ZOOM OF AORTIC VALVE WITH COLOR FLOW IMAGING
   D. SHORT AXIS AT LV LEVEL
      - BASE
      - PAPILLARY MUSCLE LEVEL
      - APEX
      - M-MODE AT PAPILLARY MUSCLE LEVEL

2. APICAL WINDOWS
   A. APICAL 4 CHAMBER
      - INCLUDING ATRIA AND RIGHT VENTRICLE
      - COLOR FLOW ON MITRAL VALVE
      - COLOR FLOW ON TRICUSPID VALVE
      - CW DOPPLER OF TR VELOCITY
      - MITRAL INFLOW PW DOPPLER AT LEAFLET TIPS
      - PULMONARY VEIN PW DOPPLER
      - MITRAL VALVE (NO COLOR)
      - MITRAL MEDIAL ANNULUS TISSUE DOPPLER IMAGING VELOCITIES
      - MITRAL LATERAL ANNULUS TISSUE DOPPLER IMAGING VELOCITIES
      - TRICUSPID LATERAL ANNULUS TISSUE DOPPLER IMAGING VELOCITIES
      - CW DOPPLER OF MR FOR PEAK VELOCITY AND TVI*
      - IF MR > MILD BY COLOR FLOW IMAGING, PISA RADIUS FOR MR†
B. **Apical Long Axis (Includes LVOT)**
- Including Atria and Right Ventricle
- Color on Mitral Valve
- Zoom of Mitral Valve (No Color)
- Color on LVOT/ Aortic Valve
- PW Doppler of LVOT Velocity
- CW Doppler of Peak Aortic Valve Velocity
- Depth Changed for LV Only
- Depth Changed for LA Only (for Volumes)

C. **Apical 2 Chamber**
- Including Atria
- Color on Mitral Valve
- Zoom View of Mitral Valve (No Color)
- Depth Changed for LV Only (for Volumes)

3. **Subcostal Windows**
- Long Axis View of LV and RV (4 Chamber)
- IVC

*Record highest MR CW Doppler Peak Velocity and TVI from any apical view
†Record best PISA radius from any apical view
‡If poor endocardial definition, administer contrast
APPENDIX 2
HFN ECHO CORE LAB SHIPMENT FORM

To: HFN Trials
From: ________________________________
Echo Core Lab
Site Name/Number ________________________________
Plummer 115
200 First Street, SW
Rochester, MN 55905
Contact Person: ________________________________
Attn: Barbara Manahan
Fax: ________________________________
Fax: 507-266-2532
Telephone: ________________________________
Telephone: 507-266-0072
Date: ___/____/_____ ___/___/____

<table>
<thead>
<tr>
<th>HFN ID#</th>
<th>Patient initials</th>
<th>Echo Date</th>
<th>Scan description</th>
<th>Number of Clips</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
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<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Instructions:

If using Heart IT transfer system:
Fax a copy of completed form to the Echo Core Lab, 507-266-2532.
Keep this form for your records.
Include a completed study specific Patient Information Form for each study in the shipment. ie RELAX or SMMART

If NOT using Heart IT transfer system:
Fax a copy of completed form to the Echo Core Lab, 507-266-2532.
Make a copy of this form for your records.
Enclose this form as packing slip with shipment of echocardiograms.
Include a completed study specific Patient Information Form for each study in the shipment. ie RELAX or SMMART

Signature of Sender ________________________________ Date ________________________________
APPENDIX 3

Instructions for Shipment Form

Instructions for **Echo Core Laboratory Shipment Form**:
1. One copy faxed to Echo Core Lab with each study.
2. If mailing videotape or CD, include a copy with shipment.
3. Record Echo site, date of study, shipment date, contact information (phone and fax, name of contact person) for site
4. Sign and date each form before shipping

The Shipment Form includes the address, phone number and fax number of the Echo Core Lab.

**HFN ID Number, Patient Initials, Echo Date and Scan Description** (e.g. baseline, 6, 12, or 18 month echo, or end of study echo) should be completed for each echo included in the shipment. A comment section is available and may be used as needed. (More than one shipping form may be used if necessary.)

Fax a copy of the completed shipment form to the Echo Core Lab.
   Fax number: 507-266-2532

Make a copy of the shipment form for your records.

Enclose the completed shipment form as the packing slip with the shipment of echocardiograms.

Remember to include your Patient Information Form(s) with the shipment.
# APPENDIX 4

## Echo for RELAX-HFN Trial

### Patient Information Form

<table>
<thead>
<tr>
<th>Site Name</th>
<th>Site Number</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(first three digits of subject ID number)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Study ID Number</th>
<th>Patient Initials (first, middle and last)</th>
<th>Date of Birth (example: 22/ DEC/2003)</th>
</tr>
</thead>
<tbody>
<tr>
<td>RX ___ ___ ___- ___ ___ ___</td>
<td>___ ___ ___</td>
<td>Day  Month  Year</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ECHO Date (example: 22/ DEC/2003)</th>
<th>ECHO Visit (check one)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Day  Month  Year</td>
<td>Baseline  24 week</td>
</tr>
<tr>
<td></td>
<td>Other (describe)</td>
</tr>
</tbody>
</table>

### Patient History

<table>
<thead>
<tr>
<th>Gender</th>
<th>Height</th>
<th>Weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ Male</td>
<td>cm</td>
<td>kg</td>
</tr>
<tr>
<td>☐ Female</td>
<td>inches</td>
<td>pounds</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Heart Rate</th>
<th>Blood Pressure</th>
<th>Rhythm:</th>
</tr>
</thead>
<tbody>
<tr>
<td>___ ___ ___ bpm</td>
<td>___ ___ / ___ ___</td>
<td>NSR  A Fib</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Other, specify</td>
</tr>
</tbody>
</table>

Sonographer (print name): ________________________________

Physician (print name): ________________________________

Comments to Reviewer:

---

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## Echo for SMMART-HFN Trial
### Patient Information Form

<table>
<thead>
<tr>
<th>Site Name</th>
<th>Site Number</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(first three digits of subject ID number)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Study ID Number</th>
<th>Patient Initials</th>
<th>Date of Birth</th>
</tr>
</thead>
<tbody>
<tr>
<td>SM __ __ - __ __</td>
<td>__ __ __</td>
<td>__ __ __ / __ __ __</td>
</tr>
<tr>
<td></td>
<td>(first, middle and last)</td>
<td>Day Month Year</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ECHO Date (example: 22/ DEC/2003)</th>
<th>ECHO Visit (check one)</th>
</tr>
</thead>
<tbody>
<tr>
<td>__ __ __ / __ __ __</td>
<td>Baseline 6 Mon 12 Mon 18 Mon Other (describe)</td>
</tr>
<tr>
<td>Day Month Year</td>
<td></td>
</tr>
</tbody>
</table>

### Patient History

<table>
<thead>
<tr>
<th>Gender</th>
<th>Height</th>
<th>Weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>____ cm</td>
<td>____ kg</td>
</tr>
<tr>
<td>Female</td>
<td>____ inches</td>
<td>____ pounds</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Heart Rate</th>
<th>Blood Pressure</th>
<th>Rhythm</th>
</tr>
</thead>
<tbody>
<tr>
<td>____ ___ bpm</td>
<td>____ ___ / ____ ___</td>
<td>NSR A Fib Other, specify</td>
</tr>
</tbody>
</table>

Sonographer (print name): ____________________________

Physician (print name): ____________________________

Comments to Reviewer:

---

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APPENDIX 5
Instructions for Patient Information Form

A Patient Information Form is to accompany each echocardiographic study sent to the Echo Core Lab. Please be as thorough as possible when filling out these forms.

Please indicate the name and site number of the medical facility in the Site section of the form.

This form contains the Patient Initials and HFN ID Number. The HFN ID Number should be the patient’s randomized study ID number, not their hospital or clinic ID number. HFN ID for SMMART is SM100-001 (site 100, 1st patient). HFN ID for RELAX is RX 100-001 (site 100, 1st patient). TEST 1, TEST 2 etc. may be used for the certification echoes instead of an ID number and/or initials.

Please indicate the type of exam (scan description) performed. Baseline should be checked for the echo performed during the run-in period. 6 month should be checked for the 6 month follow-up echo exam. 12 month should be checked for the 12 month follow-up exam. 18 month should be checked for the 18 month follow-up exam. Other should be checked if the echo is obtained within any other time frame. If Other is used please document the time frame from randomization in the free form section.

The Echo Date should be listed with the day first. This is followed by the first 3 letters of the month and the year. Months should be listed as:

<table>
<thead>
<tr>
<th>Month</th>
<th>Abbreviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>January</td>
<td>Jan</td>
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<tr>
<td>February</td>
<td>Feb</td>
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<td>March</td>
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<td>October</td>
<td>Oct</td>
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<tr>
<td>November</td>
<td>Nov</td>
</tr>
<tr>
<td>December</td>
<td>Dec</td>
</tr>
</tbody>
</table>

A brief patient history section is included on the form.

Gender should be indicated by a check in the appropriate box.
Birthdate should be entered in the same manner as the echo date with day first, first 3 letters of the month, followed by the year.

Height can be entered as either centimeters or inches. A check mark should be placed in the appropriate box indicating whether the measurement is in centimeters or inches.

Weight can be entered as either kilograms or pounds. A check mark should be placed in the appropriate box indicating whether the measurement is in kilograms or pounds.

A resting Blood Pressure should be obtained at the time of the echo exam. This value should be recorded on the Echo Core Lab Information Form.

Whenever possible, record the Heart Rate at the time the left ventricular outflow tract pulsed-wave Doppler exam is performed.

Please specify the patients dominant Rhythm at the time of the echocardiogram by placing a check mark in the box. An “other” category is included with space for specifying and should be used as needed.

Please print the name of the Sonographer and the Physician involved with the echo exam on the form.

A section has been included for Comments to Reviewer. This section may be used to indicate any additional information to the Echo Core Lab personnel.

Please use “NA” for information that you are unable to obtain. Record this in the designated area on the form.
### APPENDIX 6
Echo Certification Submission Form

<table>
<thead>
<tr>
<th>Site/Number</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Certification Number</th>
</tr>
</thead>
</table>

**Echo Submitted by** (please print)

_______________________________________

e-mail ______________________________________

Phone number _______________________________

Sonographer (print name)

________________________________________

Physician (print name)

________________________________________

Would you like this echo returned? □ YES □ NO

Comments to Reviewer:

________________________________________

________________________________________

________________________________________
APPENDIX 7
Submission Instructions for Echo Certification for Heart Failure Network Trials.

The Echo Laboratory at each clinical site will need to be certified prior to the enrollment of the first patient in the HFN Trial. For Certification each center is required at minimum to send one or more studies that meet the parameters listed on the “Echo Checklist” (found in Appendix 1 the Echocardiographic Manual of Operation).

The echoes will be evaluated for technical aspects and echocardiographic data based on the following information:

1) Ability to view real time and still images (this includes ability to download study from cd’s to the Mayo Echo Core Lab equipment).
2) Color flow images appear in color
3) Size of file reasonable for long term storage
4) Calibration markers appear on images
5) Satisfactory simultaneous ECG recording
6) Satisfactory view for evaluation of LV volume and EF
7) Satisfactory data acquisition for stroke volume calculation
8) Quantitative assessment of MR (color flow, PISA, vena contracta)
9) Mitral inflow velocity for diastolic function assessment
10) Doppler tissue imaging (DTI) for diastolic function assessment

*Subsequent measurements may be required for certification if further echocardiographic data are requested by other trials in the HFN.

A de-identified copy of the echo(es) should be submitted to the Mayo Echo Core Lab (shipping address below). Please submit the echo on a CD or videotape.

*All CD Dicom data must be submitted in True or Pure Dicom format.
Suggested codes:
Indeo 5.x
Microsoft Video 1
Cinepak
CDs may also be submitted using AVI and JPEG files.

For NTSC:
All video files must be in the (.avi) format
All video files must be 640x480 pixel size

All still images must be in the (.jpeg) format
All still images must be 640x480 pixel size

The Mayo Echo Core Lab cannot accept raw dicom; (.mpg) or (.wmv) format.

Each echo submitted per clinical center for certification should be labeled numerically as Test 1, Test 2 etc. Please label media with your clinical center ID number and the appropriate Test echo number.

Complete an Echo Certification Submission Form for each echo submitted and include it along with the echo in the shipment to the Mayo Echo Core Lab:
SHIPPING ADDRESS
Echo Core Laboratory
Mayo Clinic
Plummer 115
200 First Avenue SW
Rochester, MN 55905

PHONE NUMBER
507-266-0072

FAX NUMBER
507-266-2532

The certification forms completed by the Mayo Echo Core Lab will refer to the site number and test echo number.

If a center fails to meet the echo certification they will be requested to submit further echoes.

An Echo Certification Form For Heart Failure Network will be completed on the certification echo(es). Completed certification forms will be sent to the study coordinator at the clinical center. A copy of the certification forms will be sent to DCRI.
E. MISCELLANEOUS INFORMATION

1. **Process Flow for Study TTEs**

   1. Attach ECG electrodes from the ultrasound machine to patient being certain an adequate signal is obtained. *The ECG will be used for timing of echo measurements by the Echo Core Lab. Most echo values will not be measured on studies with poor quality ECG or those without an ECG.*

   2. Perform echocardiogram. Recommended number of cardiac cycles per view: videotape = 10; digital images = 5.

   3. For digital clips: Upload digital images via Heart-IT.

   4. For non-digital (VHS tape): Make copy of echocardiogram on videotape or CD*. Suggested file size for CDs: 150-250 MB.

   5. Complete the echo label.

   6. Place label on the non-recordable side of CD. Ensure label is within the boundaries of the CD.

   7. Place label on the top center label section or spine of videotape.

   8. Complete the Shipment Form.

   9. Send Shipment Form and copy of echocardiogram to the Mayo Core Laboratory, using prepaid pre-addressed Fed-Ex airbill.

   10. Retain the original echocardiogram at your site.

   *All CD Dicom data must be submitted in True or Pure Dicom format.

   Suggested codes:
   - Indeo 5.x
   - Microsoft Video 1
   - Cinepak
   - CDs may also be submitted using AVI and JPEG files.

   For NTSC:
   - All video files must be in the (.avi) format
   - All video files must be 640x480 pixel size
   - All still images must be in the (.jpeg) format
   - All still images must be 640x480 pixel size

   The Mayo Echo Core Lab cannot accept raw dicom; (.mpg) or (.wmv) format.

2. **Requirements**

   1. De-identify echo images of information such as subject name, hospital ID, etc.

   2. For digital clips: Upload de-identified data to Heart-IT with HFN patient ID number. Fax patient information form.

   3. For non-digital (videotape): Complete media label, place on the echocardiogram.

   4. Complete Shipment Form and Patient Information Form.

   5. Submit Shipment Form along with the echocardiograms, using the provided pre-addressed Fed-Ex airbills, to the Mayo Echo Core Laboratory.
3. Examples of Technical Problems with Echocardigraphic Recordings

- **Wrong format; size of echo.** To avoid submitting echoes in the wrong format or files that are too large please see section III, Process Flow for Study Echoes.

- **Make sure you can view the images at site before submission.** It is not uncommon to receive blank, corrupt, or damaged CDs or videotapes. To avoid this problem please review the CD or videotape you will be submitting prior to shipment.

- **Raw data.** Some ultrasound machines are pre-set to store echo images in “raw” data format. Before making CDs please check your equipment to ensure “true” or “pure” Dicom has been selected.

- **Unable to determine the correct echocardiographic study.** When multiple de-identified echocardiograms are submitted for the same patient on the same CD we are unable to determine the study for analysis. Even though the date may appear on the folder on CD it does not transfer with the images. Please copy only the echo that is to analyzed onto the CD.

- **Make sure burn sessions have been completed so they can be read on any computer.** Occasionally the Mayo Echo Core Lab receives CDs in which the burn session was not completed. This makes the CD unreadable. Please complete the burn sessions before submission.

- **Name the Dicom dir file.** When de-identifying the digital echocardiograms please rename or change the Dicom dir file rather than eliminating completely. The study ID number works well for this.

- **Use new video tape.** Use of pre-used videotapes degrades the echo images. Please use a new videotape for each study when submitting echoes on videotape.

- **Unable to upload to HEART IT.** See HEART-IT Manual of Operations

1. Frequently Asked Questions and Technical Considerations

- **Do we need to make the measurements?**

  The Mayo Echo Core Lab will make the measurements for the study. If measurements are needed by site for inclusion/exclusion criteria or for clinical assessment they should be performed by the site. To aid the Mayo Echo Core Lab be sure to include images without measurements in the echocardiogram.

- **Should the PISA radius be recorded as a still frame or real time image?.**

  Unless the site needs this information clinically it is not necessary to measure the PISA radius. After shifting the baseline on the color-flow Doppler and optimizing the images, PISA radius information should be recorded in real time for Mayo Echo Core Lab analysis.

- **Will we receive an echo report from the Mayo Echo Core Lab?**

  There will be no echo reports issued to the sites by the Mayo Echo Core Lab. The echoes submitted are analyzed for research purposes only.

- **Is it okay to submit an echo with measurements or do we need to delete before submission?**

  Submitting echoes containing measurements is perfectly acceptable. The Core Lab will make the measurements that are submitted on the case report forms to the trial sponsor.
• **Use of Res/Zoom feature.**

   The Res/Zoom feature should be used when recording LA and LV chambers for volumetric assessment from the apical views. The entire designated chamber and its associated walls should be visible on these images.

• **Automatic Doppler update.**

   In order to better delineate the Doppler wave patterns the automatic Doppler update feature should be paused when recording Doppler signals.

• **Avoid foreshortening of images.**

   To help avoid foreshortening the images attempt to obtain 2D images while the patient is holding a deep breath.

• **Doppler and M-mode sweep speeds.**

   Record Doppler and M-Mode at a sweep speed of 50-100 msec.

5. **Questions?**

   If you have any questions, please call the Mayo Echo Core Laboratory at 507-266-0072. If after normal business hours, please leave a detailed message including your name, study name, and telephone number. Your call will be returned as soon as possible.