# SEARCH 4 MOP
# Section 15 - Echocardiography (ECHO)
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# 15.Echocardiography

15.1. PURPOSE

Diabetes can affect the structure and the functioning of the heart. Echocardiograms are being performed on a subset of the cohort in-person participants to identify early changes that may be affecting the heart.

15.2. CERTIFICATION

Echocardiograms will be performed by sonographers. Sonographers will be trained and certified by Elaine Urbina.

15.3. OVERVIEW OF TESTING

The sonographer will obtain the following information from study personnel:

- PID (participant ID)
- Height
- Weight
- Blood pressure.

The sonographer will apply ECG leads (Black to Left arm or shoulder, White to Right arm or shoulder, Red to abdomen to far right of umbilicus below right costophrenic angle). Adjust ECG size and position so R wave is twice as high as T wave. Always use a **sweep speed of 100**. Position the subject supine, left lateral decubitus position. The sonographer will capture **at least 3 measurable heart beats of all images**: USE SLIGHTLY HIGHER GAIN than used for a clinical study.

**Parasternal Long Axis**:

2-D image of LV and Aorta

2-D guided M-Mode of LV

2-D guided M-mode of LA and Aorta

**Parasternal Short Axis:**

2-D images of LV (sweep from papillary muscle level through Mitral Valve to base of the heart)

2-D guided M-mode of LV from short axis

**Apical 4 Chamber:**

2-D image of inverted Apical 4 chamber(with entire left atrium visible)

2-D image of inverted Apical 2 chamber

Doppler Mitral Valve (obtain at least 3 E and A waves)

TVI of Mitral Valve annulus (septal [medial] and free wall [lateral])

The length of the echocardiogram will be less than 30 minutes.

15.4. RECORDING OF TEST

The sonographer will obtain the following from study personnel prior to the testing: worksheets and disks. Both the worksheet and the disk will be labeled with the following information: study name (SEARCH4), site name, subject ID, and date of study. Names are not to be written on worksheets or disks.

- Enter into echo machine only:
  - Patient's SEARCH4 subject ID number
  - Subject name (this will be removed with anonymization button later)
  - Date of the study
  - Sonographer initials
- Annotate on the screen: SEARCH4 ID
- Subject NAME must be entered into echo machine so that if abnormalities are noted during clinical 'over-reading' by a cardiologist, the correct subject information is available to contact the person and their MD. However, echos should be 'de-identified' for the research reading.
- Accomplish this by hitting the "de-identify" button on your echo machine while scanning. Consult your application specialist for details specific for your echo machine.
- Many sites require sonographers to enter the subject's MRN. Another field may be used for the research ID number as long as the same field is always used.

The sonographer will complete the worksheet during the echo visit. See Appendix A for a copy of the worksheet.

The sonographer will copy the echo images in DICOM format to the disk.

Each site will designate study personnel responsible for scanning the worksheet and uploading both the worksheet and the images from disk to the Intelemage website. Each site will store the worksheet and the disk in the participant's study chart or another secure location.

## 15.5. INTELEMAGE ACCESS AND REPORTS

Local sonographers and project managers will be given access to the Intelemage website. The CCHMC sonographer will generate and send reports to the Coordinating Center on a regular basis.

## 15.6. REPORTING ECHOCARDIOGRAMS THAT ARE NOT PERFORMED

Echocardiograms are being performed on a subset of the cohort in-person participants. The Coordinating Center will designate which subjects are eligible for an echocardiogram. There may be occasions when a subject who is eligible for an echocardiogram may complete a cohort visit, but no echocardiogram was performed. This may be due to participant refusal or some other issue. When a subject completes a cohort visit, but does not have an echocardiogram performed, study personnel will complete an Echo Not Completed form. See Appendix B for a copy of this form.

## 15.7. FLAG ALERTS

### 15.7.1. *Flag Criteria*

- Reduced systolic function as defined by a shortening fraction of < 25% or significant wall motion abnormalities
- Cardiomyopathy (hypertrophic/dilated)
- Coarctation of the aorta
- Significant arrhythmia - (SVT, atrial fib/flutter, frequent PVCs, VT, 2$^{nd}$ & 3$^{rd}$ degree heart block) especially if subject has dizziness, shortness of breath, chest pain or other symptoms
- HR > 150 or < 50
- Valvular disease (insufficiency or stenosis > mild, significant MVP)
- Findings of congenital heart disease
- Pericardial effusion
- Vegetation/tumor
- Other abnormalities considered significant findings by the observer Left
- Ventricular hypertrophy = LVM > 51gm/ht$^{2.7}$

### 15.7.2. *Flag Procedure*

#### 15.7.2.1. Sonographer

- Identify studies to be flagged at the time of scanning

- Initiate a FLAG letter by entering the Subject's PID and date of the echo visit. See Appendix C for a copy of the FLAG letter.
- Indicate the severity and add the abnormality noted
- Save the letter as "SEARCH FLAG *XXXXXXXX*" (fill in PID)
- Call local project manager and send project manager a copy of the FLAG letter via email.

15.7.2.2. Project manager

- Add the name and phone number of the local principal investigator.
- Save letter and send copies to the following via email:
  - local principal investigator
  - CCHMC sonographer readers:
    - Stephanie.Stewart@cchmc.org
    - Lauren.Longshore@cchmc.org
  - SEARCH Echo Core PI: Elaine.Urbina@cchmc.org
  - CCHMC Echo Lab physician: Michael.Taylor1@cchmc.org
- Call Dr. Urbina's administrative assistant Melinda Andrews at (513) 636 8265. She will contact Dr. Urbina; or if she is not available, she will contact the physicians reading echos at CCHMC that day to alert them that an echo has been "flagged."

15.7.2.3. Physician reader

- Review images
- Determine if the condition is considered serious.
  - If serious, call the principal investigator at the local site. Then reader will email the letter to Dr. Urbina.
  - If not serious, correct the Flag letter as needed and email to Dr. Urbina, who will communicate with the principal investigator.
- The physician will then complete the final reading within Echo IMS.

15.7.2.4. Echo Core principal investigator

- Will review the echo and the flag letter and will:
  - Follow up with principal investigator at the local site as needed for serious conditions. Principal investigator will then contact subject by telephone.

- For minor conditions, Dr. Urbina will determine if abnormalities should be reported to the subject directly. If reporting deemed necessary, she will send Flag letter back to project manager. Local principal investigator or designee will then contact subject by telephone or via mailed letter. If contacting by letter, the Flag letter will be updated with the name and address of the subject prior to mailing.

15.8. QUESTIONS

For any questions contact:

Elaine M. Urbina, MD, MS.

Director, Preventive Cardiology

Cincinnati Children's Hospital Medical Center

Attn: Melinda Andrews

3333 Burnet Ave.

MLC 7002

Cincinnati, OH 45229

513-636-8265

Melinda.Andrews@cchmc.org

Or Stephanie Stewart (sonographer)

Stephanie.Stewart@cchmc.org

Appendix A: Echo Worksheet

# SEARCH4 Sonographer Echo Scanning Worksheet

SEARCH4 Subject ID #: _____

Sonographer Initials: _____

Date of Study: _____

☐ SEARCH4 echo protocol completed including **10 cardiac cycles per image at 100 mm/sec sweep speed** for each of the following 10 images (or notes made for missing images).

| **Image No.** | **Image** | **Done** (Y or N) | **Notes** (abnormalities, reasons for non-completion) |
|---|---|---|---|
| 1 | **Parasternal Long-Axis Image** | | |
| 2 | **PLAX 2D-guided M-Mode of LV** | | |
| 3 | **PLAX 2D-guided M-Mode of LA and Aorta** | | |
| 4 | **2D-parasternal short-axis image (papillary muscle level)** | | |
| 5 | **Short axis 2D-guided M-Mode of LV** | | |
| 6 | **2D Apical 4-chamber image** | | |
| 7 | **2D Apical 2-chamber image** | | |
| 8 | **Mitral Inflow Pulse Wave Doppler** | | |
| 9 | **Pulse Wave Tissue Doppler Imaging at MEDIAL mitral annulus** | | |
| 10 | **Pulse Wave Tissue Doppler Imaging at LATERAL mitral annulus** | | |

☐ Subject ID written correctly on disk (no patient name is to be listed on disk or worksheet)

☐ "Flag Alert" protocol followed (check only if abnormality noted on echo)

☐ Study & Form uploaded to Intelemage site

Other comments:

Appendix B: Echo Not Completed Form

PID: __ __ __ __ __ __ __ __

Reason Echo was not performed

- ☐ Participant refused
- ☐ Other: _____

Date Completed: _____ Staff ID: _____

Date Reviewed: _____ Staff ID: _____

Date Entered: _____ Staff ID: _____

Appendix C: Flag Alert Letter

PID: __ __ __ __ __ __ __ __

Date of Echo visit: _____

***Name of participant or parent*** *(to be completed by Project Manager when ready to send letter)*
***Address***
***City, State Zip code***

Dear ***Name of participant or parent***,

Thank you for participating in the SEARCH Study**.**

An abnormality was noted in the echocardiogram performed as part of the study.

Degree of abnormality ☐ mild ☐ moderate ☐ severe

Abnormality noted: _____

For more information, please contact the principal investigator: _____

at (____) _____ - _____

These measurements were obtained as part of a research study and do not represent a medical diagnosis. We recommend a complete clinical study. If you would like for us to arrange this, please call the number listed above.

Again thank you for your time and dedication to helping us learn more about Diabetes and Cardiovascular diseases.

Sincerely,

***Name of principal investigator***