EXIT SUMMARY

1 Background and Rationale

This is a checklist and summary data form. Participant identification and findings from the Home Interview and the Baseline Clinic Interview and the Examination are summarized on this computer-generated form. The information is reviewed and confirmed if necessary in a meeting between the study participant and a Nurse Practitioner/Physician Assistant. The Exit Interview has three purposes.

- It serves to collect findings of potential medical significance, call them to the attention of the Nurse Practitioner/Physician Assistant, and aid in the review or confirmation of these findings.
- During the Exit Interview process, the participant has the opportunity to discuss the significance of any medical history or physical examination findings.
- Recent changes in the participant's health status or findings requiring immediate medical attention (so-called "alerts") will be acted upon by the Nurse Practitioner/ Physician Assistant. Advice and referral are offered as appropriate at this point. A physician will be available for consultation. All Exit Summary Forms must be reviewed by a physician, preferably within days of the clinic visit.

2 **Definitions**

Not applicable.

3 Methods

3.1 Exit Interview Procedure

At the time of the Exit Interview the participant is

- Briefed on the principle findings;
- Given an opportunity to ask questions related to interviews and examinations;
- Informed that a complete report of the findings will be mailed to him/her and to his/her physician within two to three months.
- Thanked for his/her time and effort.
- 3.2 <u>Notification of Results</u>
 - Since CHS is a research program, the study assumes no responsibility for the participants' medical care. Referral to local sources of care is a service provided to the participants.

- Each Clinic must consider its local situation and consult with the medical community to assure that the study's objectives, expectations and obligations are clearly understood.
- 3.3 <u>Alerts Identified during CHS Clinic Visit</u>
 - The Exit Summary notes three levels of alerts:
 - IMMED indicates the highest level of alert,
 - URGENT is intermediate, and
 - ROUTINE indicates a slightly abnormal value.
- 3.4 <u>Specific details regarding Exit Summary (Data Source)</u>
 - <u>Section A</u> Participant Identification:

Contains Participant Name, ID number, Date of Birth and Date of Visit.

Section B Personal Physician (Tracking Information Form)

Contains the personal physician/clinic name.

- Section C Prescription Medications (Medications Form)
 - Contains medication name, strength, # Prescribed/day, and # Taken/day.
 - When the form contains more than three medications all medications will be listed on a separate page and the following note will appear on the Exit Summary Form.

NEED NOTE TEXT

- Section D Mood and Cognition (Depression Scale and Cognitive Function)
 - The total scores from the Depression Scale and Cognitive Function Forms are printed.
- Section E Vision and Hearing (Personal History Form)
 - Participant Responses to the Vision and Hearing questions are printed.
- Section F Medical History (Medical History Form and Neurologic History Form)
 - Participant responses to questions regarding prior history of cardiovascular

disease (myocardial infarction, congestive heart failure, claudication, and angina) are printed.

- Participant responses to questions regarding prior history of stroke and TIA are printed.
- Section <u>G</u> Recent Symptoms (Medical History Form)
 - Participant responses to questions regarding recent symptoms (shortness of breath, palpitations, indigestion, chest pain) are printed.
- Section H Possible Congestive Heart Failure (Medical History Form)
 - Participant responses to the questions regarding possible symptoms of congestive heart failure are printed.
- <u>Section I</u> Pulmonary Function Test Report
 - The results of the pulmonary function test are reported.
- Section J Blood Pressure (Random Zero Seated Blood Pressure)
 - The values for both Blood Pressure measurements are reported.
 - An alert is noted when either reading is abnormal.
- Section K Neurological Examination (Physical Examination Form)
 - Results of the Neurological examination are reported.
- Section L Potentially Significant Findings
 - The following data are entered by the ECG, Echocardiography and Ultrasound technicians.

Was the test complete? If not, why not? Were any alerts noted? If so, what were they?

This information is used to identify alerts for the Exit Summary.

• Additional alerts may be identified following Reading Center interpretation.

- Section M Relevant Incidents
 - Unusual events not recorded elsewhere are written on the Exit Summary Form by the a CHS staff member, or the interviewer conducting the Exit Interview.
 - Examples of such incidents include participant fainting, falling down, or otherwise injured in the clinic.
 - Unless an incident occurs this section is blank.
- Section N
 - A summary of all forms/stations which contain alert values is printed
- Section O Other Alerts Identified During Exit Interview
 - Alerts such as unstable angina require the Nurse Practitioner/Physician Assistant to look for an indication of angina on the Exit Summary and then ask probing questions in order to make a determination. Any alerts identified through this type of questioning will be listed here. This procedure must be standardized among the clinics.
- <u>Section P</u> Alerts/Action Required/Date Action Taken
 - All alerts identified during the Clinic Visit should be listed in Section P. This includes
 - Computer-identified alerts listed in Sections N (listed again here in Section P).
 - Alerts identified in Section O (Exit Interview).
 - The Exit Interviewer and/or other clinic staff member records information regarding:
 - Action Required:

Record the details regarding the action required for the given alert.

NOTE: Appropriate actions include sending letters to physicians, calling physicians, notification of the clinic physician, etc.

- Date Action Taken:

Record the month, day and year an action was taken.

- Section Q Exit Interviewer Code
 - Record the three digit code of the Exit Interviewer.

3.5 <u>Sections R through V</u>

The following sections are completed by the physician following completion of his/her review.

- Section R Physician Reviewer Code
 - Record the three digit code of the physician who reviews the Exit Summary.
- <u>Section S</u> Date of Physician Review
 - Record the date the physician completed the Exit Summary Review.
- Section T Additional Alerts noted by physician
 - Space is provided for the physician to record any additional findings requiring attention.
- Section U Modifications to Alerts in Section P
 - Space is provided for the physician to note any modifications required to the Alerts or Actions Required listed in Section P. This includes conditions listed as Alerts where on physician-review:
 - no alert is present,
 - no action is required,
 - more urgent action is required,
 - less urgent action is required.
- Section V Additional Action Required
 - Space is provided for the physician to list any additional actions required as a result of the Exit Summary review. The physician records the following information:
 - Alert requiring additional action

Record the alerts listed in Section P or T that require action not

recorded elsewhere on the Exit Summary.

- Action Required

Record the details regarding the action required for the given alert.

NOTE: Appropriate actions include sending letters to physicians, calling physicians, notification of the clinic physician, etc.

- Who is responsible for taking the action

Record the name or position of the person responsible for taking the action (e.g. physician, nurse, etc.)

- Date Action Taken:

Record the month, day and year an action was taken.

WEIGHT AND 15 FOOT WALK

4 Background and Purpose

Participant weight is measured during the Surveillance Clinic Visit to track weight changes during the interim visits. The 15-foot walk is repeated as a measure of physical function status.

5 Methods

5.1 <u>Weight Measurement</u>

Weight is measured with the participant wearing the examination suit but no shoes (the weight of the CHS examination suit will be subtracted from this weight by the computer).

- The Detecto Balance Beam Scale (Model #437) calibrated in kilograms is used to weigh the participant.
- Storage:

When not in use, the counter poise should rest in a position toward the far right, in vicinity of 200 lbs. The top poise should rest in the zero position.

- Weight measurement is done using the following procedure:
 - Prior to asking participant to step onto scale, lift the counter poise and position it at zero.
 - Ask participant to step onto the scale, facing the measurement beam.
 - Instruct participant to stand in the middle of the platform on the scale with head erect and eyes looking straight ahead.
 - Weight should be equally distributed on both feet.
 - Instruct participant not to touch or support him/herself.
 - With participant standing quietly in the proper position, examiner lifts the counterweight (larger weight), and slides it to the right until the beam approaches balance.
 - Adjust the top poise until the beam is evenly balanced.

- Read reads the scale with eyes level to the point of measurement.
- Record the weight and technician ID on the Surveillance Visit Check-Off Sheet to the nearest 0.5 pound, rounding down.
- Ask the participant to step off the scale.
- Return the counter poise to the 200-pound mark, and the top poise to zero.
- Maintenance of Balance Scale

With normal use, the scale should last for many years. In order to ensure long life, the following maintenance practices are recommended:

- The scale equipment should remain in a stationary position; it should not be moved from room to room, nor moved within the same room.
- While the upper poise slides easily across the column, the counter poise must always be lifted carefully before it is moved across the column; this prevents any wear on the notches which could result in erroneous readings.
- The counter poise should rest on the 200-pound mark when the scale is not in use; if the weight is left at zero, the gear mechanisms are subjected to unnecessary wear.
- The scale should not be tipped; the platform should be kept free of objects and no one should ever jump on it; all staff should be instructed in the correct use of the scale.
- The scale should always remain standing on a flat, hard, level surface.

5.2 <u>Fifteen Foot Walk</u>

- Is the participant able to walk 15 feet?
 - Code "Y Yes" when the participant is able to perform the 15 foot walk.
 - Code "N Not able" when the participant was not physically capable of walking. This includes a participant who is bed or wheelchair bound.

NOTE:

1) When the participant indicates that they are unsure whether they are able to do the walk, do not ask them to perform the walk.

2) When the clinician is concerned over the participant's stability or

ability to perform the walk, s/he should ask for an **assistant** to walk beside the participant.

- Code "A Not assessed" when the participant refused to do the walk or for some reason the walk was not performed other than that codable under "N Not able".
- Instructions for conducting the measured walk:
 - Demonstrate the walk for the participant.
 - The participant stands with both feet together at one end of the rule.
 - With the participant properly positioned at starting line say "Ready, Begin".
 - Start the stopwatch as the participant begins walking; stop the stopwatch when the first of the participant's feet is completely across the finish line.
- Time in seconds to walk 15 feet
 - Record the number of seconds it took the participant to walk the 15 foot course and the technician ID on the Surveillance Visit Check-Off Sheet.