

- (b) Supervision performed by the AAA Unit Manager and Director.
- (c) Feedback from participants to the Participant Advocates.
- (d) Data obtained from the Participant Satisfaction Questionnaire.

4. Driver/Courier

a. Purpose

- (1) During the conduct of the Veterans' Health Study, the primary role of the Driver/Couriers is to transport study participants between the participant lodging facility and the Lovelace clinic site and to transport participants' urine specimens to the Lovelace Clinic laboratory. Additional Driver/Courier duties include, but are not limited to, the transportation of study supplies/materials as needed.
- (2) The Driver/Couriers will report directly to the Deputy Project Director or his designated representatives.

b. Qualifications

- (1) Driver/Couriers will be selected from applicants who have demonstrated an ability to effectively operate motor vehicles as large as or larger than the study twelve (12) passenger vans and who have some familiarity with the handling of clinic supplies or research specimens. Driver/Courier applicants must have or be able to obtain a Class 10 New Mexico driving license or the equivalent.
- (2) Driver/Couriers should be able to answer participants' questions about Albuquerque, the state of New Mexico and the Southwest. Driver/Couriers should possess a high school diploma or the equivalent.

c. Procedures

Procedures to be followed by Driver/Couriers are specified according to the specific day of the week and also to which of the two working shifts the employee is assigned:

(1) A-Shift, Monday

- (a) 7:15 A.M. - Arrive at the Lovelace Clinic site and report, with the study materials delivery cart, to the clinic front door (north side of Building No. 1) no later than 7:25 A.M. Collect urine specimen collection kits from study participants as they arrive by contract bus.

- (b) Using the delivery cart, transport urine specimen collection kits to the Veterans' Health Study specimen processing center in the Lovelace Clinic Laboratory.
- (c) Return empty ice chests with ice packs to the designated equipment cleaning area, wash/clean the chests and the ice packs; return the empty ice chests to the designated storage area and place cleaned ice packs into freezer located there.
- (d) Report to the Veterans' Health Study Office (Participant) Advocate for assignment(s) as delegated by the Deputy Project Director.
- (e) 2:45 P.M. - Report to the Participant Advocate responsible for coordinating the processing of participants undergoing medical examination; under direction of that Advocate, transport participants to the study lodging facility; return study participants to the lodging facility as dispatched by the Advocate until all participants have been returned. Park the study van in the designated area and clockout.

(2) A-Shift, Tuesday through Thursday

Driver A's duties on Tuesday through Thursday are identical with the duties stated under MONDAY, except for the following:

- (a) 7:25 A.M. - When collecting urine specimen containers from arriving participants, also collect study laundry (soiled jogging suits) from participants arriving for Psychological Testing Day; after delivering urine specimens to the lab and cleaning specimen equipment, deliver laundry to the Lovelace Housekeeping Department for cleaning; pickup cleaned laundry as available.
- (b) 2:45 P.M. - Report to the Participant Advocates and UNDER THEIR DIRECTION, transport participants back to the lodging facility as described above.

(3) A-Shift, Friday

- (a) 6:30 - Pick up van from LMC parking area and drive to the Clarion Hotel.
- (b) 7:00 - Arrive at the Clarion Hotel, board twelve (12) participants into van as directed by Participant Advocate on location; depart the Clarion Hotel no later than 7:15.

- (c) 7:30 - Arrive at the north entrance of LMC Bldg. 1; allow participants to exit van and enter bldg.
 - (d) 7:35 - Report to Veterans' Health Study Lounge Secretary for assignment(s) by Deputy Project Director.
 - (e) 10:30 - Return van to LMC parking area and clock out for the weekend.
- (3) B-Shift, Monday
- (a) 6:30 - Pick up van from LMC parking area and drive to the Clarion Hotel.
 - (b) 7:00 - Arrive at Clarion Hotel, load eleven (11) urine specimen collection kits and board eleven (11) study participants; depart Clarion Hotel no later than 7:15.
 - (c) 7:30 - Arrive at north entrance to LMC Bldg. 1, allow participants to exit van and enter building.
 - (d) 7:35 - Report to Veterans' Health Study Lounge Secretary for assignment(s) by Deputy Project Director.
 - (e) 14:30 - Report to LMC lab, pick up labeled urine specimen containers for this evening's orientation; assemble and load twenty-three (23) urine specimen containers (labeled container plus two (2) frozen ice packs in an Igloo ice chest) into the van.
 - (f) 15:00 - Arrive at north entrance to LMC Bldg. 1.; pick up, up to three (3) participants and take them to the Clarion Hotel; at direction of Participant Advocate on duty in the hotel, deliver twenty-three (23) urine specimen containers to the Study orientation room.
 - (g) 16:25 - Arrive at north entrance to LMC Bldg. 1.; pick up, up to nine (9) participants and take them to the Clarion Hotel; return to LMC.
 - (h) 17:30 - Return van to LMC parking area and clockout.
- (4) B-Shift, Tuesday
- (a) 14:00 - Report to Veterans' Health Study Lounge Secretary for assignment by Deputy Project Director.
 - (b) 14:30 - Repeat "Monday (e,)", above.
 - (c) 15:00 - Repeat "Monday (f,)", above.

- (d) 16:25 - Repeat "Monday g", above.
 - (e) 17:25 - Return to LMC Bldg. 1.; pickup twelve (12) participants and take them to Clarion Hotel.
 - (f) 18:25 - Return to LMC Bldg. 1.; pickup eleven (11) participants and take them to the Clarion Hotel.
 - (g) 19:30 - Return van to LMC parking area and clockout.
- (5) B-Shift, Wednesday
- (a) Repeat TUESDAY as indicated in steps (a)-(g), above.
- (6) B-Shift, Thursday
- (a) 14:30 - Report to Veterans' Health Study Lounge Secretary. Pickup van from LMC parking area.
 - (b) 15:10 - Pickup three (3) Medical Day participants from north entrance of LMC Bldg. 1; take them to the Clarion Hotel.
 - (c) 16:30 - Pickup nine (9) Medical Day participants from LMC Bldg. 1; take them to the Clarion Hotel.
 - (d) 17:30 - Pickup twelve (12) Psychology Day participants from LMC Bldg. 1; take them to the Clarion Hotel.
 - (e) 18:30 - Pickup eleven (11) Psychology Day participants from LMC Bldg. 1; take them to the Clarion Hotel.
 - (f) 19:30 - Return van to LMC parking area, clockout.
- (7) B-Shift, Friday
- (a) 6:30 - Pickup van from LMC parking area and drive to Clarion Hotel.
 - (b) 7:00 - Board eleven (11) participants into van and depart for LMC no later than 7:15.
 - (c) 7:30 - Arrive north entrance of LMC Bldg. 1; allow participants to exit van and enter building.
 - (d) 7:40 - Report to Veterans' Health Study Lounge Secretary for assignment by Deputy Project Director.
 - (e) 17:30 - Pickup twelve (12) participants from LMC Bldg. 1; take them to the Clarion Hotel.

(f) 18:30 - Pickup eleven (11) participants from LMC Bldg. 1; take them to the Clarion Hotel.

(g) 19:30 - Return van to LMC parking area and clockout.

(8) B-Shift, Sunday

(a) 14:00 - Pickup, assemble and load twenty-three urine specimen containers into van and, at the direction of the Participant Advocate on duty, deliver them to the orientation area in the Clarion Hotel.

(b) 16:00 - Return van to LMC parking area and clockout.

d. Vehicle Maintenance

To ensure the reliable and effective operation of Veterans' Health Study vans, each Driver/Courier will be responsible for the performance of the following maintenance procedures on the van assigned to him/her. Refer to Operating Instructions Manual supplied with vehicle:

(1) Daily Vehicle Maintenance

(a) Check oil, engine coolant and windshield washer fluid levels; "top off" as necessary.

(b) Clean all windows inside and outside.

(c) Check upholstery and floors; brush/sweep as necessary to maintain a clean, pleasant appearance.

(d) Check fuel level; add fuel as necessary.

(2) Weekly Vehicle Maintenance

(a) Check tire pressures, adjust as necessary.

(b) Check automatic transmission fluid; if low, report to Deputy Project Director.

(c) Wash vehicle (Rain Tunnel Car Wash - 5101 Lomas NE)

(d) Treat all vinyl in vehicle with Armour-All.

(3) Six-Month Vehicle Maintenance

At least twice a year and more often if necessary, each vehicle is to be thoroughly cleaned inside and out, the upholstery is to be shampooed and the finish is to be paste waxed and buffed (Rain Tunnel Car Wash).

(4) Dealer Performed Maintenance

Each Driver/Courier is responsible for becoming familiar with the dealer maintenance schedules as provided in the vehicle operating manual. Each Driver/Courier is further responsible for notifying the Deputy Project Director when based on vehicle use mileage/time, dealer scheduled maintenance should be performed.

e. Confidentiality

Each Driver/Courier will be required, prior to transporting any study participants, to receive the Veterans' Health Study Assurance of Confidentiality briefing and to sign the appropriate form of acknowledgment.

f. Security

Each Driver/Courier will be responsible for the security of his/her assigned van and its study-related contents. While unoccupied, vans will be locked with vehicle ignition and door keys maintained in the possession of the assigned Driver/Courier.

g. Unauthorized Use of Veterans' Health Study Vehicles

The Veterans' Health Study vehicles are to be used only for purposes relating to study requirements. Driver/Couriers will not use vehicles for any purposes other than those stated in this manual unless AUTHORIZED BY THE PROJECT DIRECTOR, THE DUTY PROJECT DIRECTOR OR THEIR DESIGNATED REPRESENTATIVES.

h. Problems

Each Driver/Courier will immediately or at least at the next most convenient opportunity, report any problems coming to his/her attention to the Deputy Project Director or to one of the Participant Advocates.

i. Emergency Situations

Any emergency coming to the attention of a Driver/Courier will involve either the operation of the Lovelace van or the condition of one or more participants. Such emergencies will be handled as follows:

(1) Operational Emergency

- (a) If the Driver/Courier experiences a personal emergency which affects his function, he will report the emergency as soon as possible to the Deputy Project Director.

(b) If an emergency situation occurs with the operation of the Lovelace van, the Driver/Courier will report it as soon as possible to the Deputy Project Director. Such situations would include accidents, mechanical failures, etc.

(2) Participant Emergency

Should any participant experience a medical or psychological emergency while with or being transported by a Driver/Courier, the Driver/Courier will immediately proceed to the nearest phone and notify the Lovelace Emergency Center.

j. Equipment and Supplies

In the performance of their duties and responsibilities, Driver/Couriers will use and be required to account for the following:

- (1) Twelve passenger, Dodge van.
- (2) Motorola Pageboy pager.
- (3) Participant urine specimen collection kits.

k. Quality Control

The level and quality of the performance of each Driver/Courier will be monitored and controlled by the Deputy Project Director based on:

- (1) Personal observation and supervision.
- (2) Reports and feedback from the study participant advocates.
- (3) Reports and feedback from staff members of the Lovelace Medical Center lab and of the Clarion Hotel.
- (4) Data obtained from completed Participant Satisfaction Questionnaires.

5. Participant Lodging

a. Objective

During its conduct of the Veterans' Health Study, the Lovelace Medical Foundation intends to provide lodging of the highest quality to study participants at the most reasonable cost.

- (1) To meet this objective, Lovelace has made arrangements with one of Albuquerque's finest hotels to serve as a lodging facility for study participants during their stay (referred to further in this manual as the Study Lodging Facility or "the hotel").
- (2) Through these arrangements, the hotel will provide lodging for Veterans' Health Study participants and their relatives or guests, members of the Centers for Disease Control staff, study subcontractors and study consultants at reduced contract prices. Additional services provided by the hotel include free transportation by courtesy van for all study participants to and from the Albuquerque International Airport, the Albuquerque Bus Station and the Albuquerque Train Station; and full use by study participants and their guests of all facilities located in the hotel or to which hotel guests normally have access.

b. Procedures

The purpose of these procedures is to provide a smooth and efficient interaction between Veterans' Health Study Logistics management and staff members and members of the hotel staff. Such efficient coordination will ensure the comfortable and convenient lodging of study participants, their guests and study associated personnel.

(1) Hotel Room Reservations

- (a) At the beginning of each calendar quarter, the Lovelace Veterans' Health Study Deputy Director will provide the hotel with an estimate of the anticipated study room requirements for the following three-month period. Room requirement estimates may be modified as the Schedulers schedule potential study participants.
- (b) The study Deputy Director will provide the hotel with names of all study participants who are scheduled to arrive no earlier than seventy-two hours (72) hence and no later than one hundred and fifty hours hence. These names will be given only to designated members of the hotel's reservations staff, as required by the confidentiality agreement (see below). Confirmed room reservations may be modified as required to meet participant needs.

c. Participant Transportation

- (1) Study participants will be transported from/to the Albuquerque International Airport, Bus Station or Train Station to/from the hotel in the hotel's courtesy vans which will, if necessary to meet participant arrival/departure

schedules, provide "pick-up/drop-off" service as frequently as each half hour.

- (2) Study participants will have been informed as to how to access transportation to the hotel by a hotel courtesy van. This information will come from prearrival mailings and phone conversations with Participant Advocates. The participant is told to contact the hotel courtesy van dispatcher by phones located in the Albuquerque International Airport, the Albuquerque Train Station or the Albuquerque Bus Station. He is to inform the answering staff member that he is a hotel guest at the (airport, train station or bus station) needing transportation to the hotel. After waiting an intended maximum of thirty (30) minutes, the participant will be picked up by the courtesy van and transported to the hotel.

d. Participant Hotel Registration and Checkout

The following procedures will help to ensure that each study participant experiences as little inconvenience as possible when he is either registering with or checking out of the Study Lodging Facility.

- (1) When he arrives at the hotel, each study participant, based on instructions previously provided through mailings and Participant Advocate phone calls, will:
 - (a) Register for his hotel room by signing the guest register with his name only. He will not provide his home address or any other identifying information. Exceptions will be participants who have ELECTED to arrive one or more days early (at their own personal expense) to sightsee or tour the area. Such participants will register with the hotel as would any other guest. Then, on their scheduled day of arrival FOR STUDY PARTICIPATION, such participants will re-register as indicated in the first instance above. The Participant Advocate will be responsible for reminding the participant to reregister.
 - (b) Remind the desk clerk that he is expecting a message. This message, either in the form of a written note or oral instructions from the desk clerk, will instruct the participant when and where to meet his assigned study Advocate (See this manual, Participant Advocate section).
- (2) On the day that each participant's STUDY REQUIRED hotel lodging ends, he will do one of the following:

- (a) With assistance as needed from his assigned Advocate, each study participant will checkout of his hotel room no later than 1:00 p.m. (or at an earlier time if necessary to ensure scheduled connections with a common carrier).
- (b) If necessary, a participant may arrange with his assigned Advocate to be allowed to remain in his hotel room as late as 2:00 p.m. on checkout day.
- (c) If the participant intends to remain in his hotel room beyond his study-required stay, he may do so at the same negotiated discounted room rate. The procedure for continued stay at the hotel will be to checkout of the hotel by 1:00 p.m. and to re-register as any other private hotel guest. The Participant Advocate will assist with this process as needed.

e. Participant Meals at Hotel

Study participants will be furnished all meals during their study required stay in Albuquerque. Breakfast on the medical and psychological testing days will be provided buffet style at the test center. Breakfast on the debriefing day will be at the hotel. Participants will be able to choose breakfast of their choice. Payment for this meal, and all other meals except as discussed above, is described in the following sections of the manual.

f. Relatives or Guests of Participants

Under the terms of the hotel contract, each study participant may house, in addition to himself, up to three guests in his hotel room, at no additional cost either to Lovelace or to the participant. This includes situations where a participant arrives one or more days early or extends his stay by one or more days to sightsee, visit or tour the area. Study participants will have been informed, orally and in writing, prior to their departure for Albuquerque, that ALL OTHER EXPENSES ASSOCIATED WITH BRINGING RELATIVES OR GUESTS WILL BE THEIR OWN RESPONSIBILITY. This includes relatives' (guests') meals, entertainment and transportation.

g. Incidental Charges Incurred by Participants

- (1) To protect the confidentiality of participants' identities, and to provide for manageable accounting of lodging facility charges, incidental expenses incurred by study participants will not be charged to the invoice submitted to Lovelace Medical Foundation. Such incidental expenses may include charges for long distance phone calls, room service and meals other than those specifically provided by Lovelace.

(2) So that study participants may enjoy, at THEIR OPTION hotel services which normally generate incidental room charges, the following procedure will be required, and will be plainly communicated to each study participant no later than the conclusion of Day One Orientation:

- (a) The participant will notify the hotel registration desk clerk that he wishes to establish a private individual account.
- (b) The participant will provide the registration desk clerk with either an acceptable credit card number or with a \$25.00 cash deposit.
- (c) The hotel will establish a private charge account for the participant. This account will IN NO MANNER link the participant with the Lovelace Medical Foundation, the Veterans' Health Study or the Centers for Disease Control. Such a private account will however, link the participant to Albuquerque, New Mexico and to the lodging facility.
- (d) Such a private account will be completely settled with the concerned participant when he checks out of his hotel room. IN NO INSTANCE WILL THE LOVELACE MEDICAL CENTER BE HELD RESPONSIBLE FOR ANY EXPENSE CHARGED TO A PRIVATE INDIVIDUAL ACCOUNT ESTABLISHED BY ANY STUDY PARTICIPANT.

h. Cost Control

The costs of lodging study participants will be managed and contained through application of the following practices:

- (1) Strong support of the arrangements agreed upon by the Lovelace Medical Foundation and the lodging facility, prohibiting the charging of incidental expenses incurred by study participants to the Lovelace account.
- (2) Accurate accounting for "pre-examination" and "during examination" cancellations by participants, and reporting of cancellations to the lodging facility as required. Such accounting and reporting are the responsibility of the Deputy Project Director.
- (3) Prompt reporting to the lodging facility of room or block-of-room cancellations. Such reporting is the responsibility of the Deputy Project Director.

i. Veterans' Health Study Satellite Office

The lodging facility has agreed to provide the Lovelace Medical Foundation, with leased office space to be used for:

- (1) Six (6) consultation rooms in which participant examination results interviews (medical and psychological) will be conducted.
- (2) An office for the use of the study Participant Advocates while they are in the hotel.
- (3) An open waiting area for the use of participants who are reporting for Day One orientation or who are waiting for their scheduled results interviews.
- (4) A separate area containing offices, testing rooms and a lounge/meal room to be used for the conduct of Psychological testing.

j. Security and Confidentiality

The security and confidentiality of study-related data, which is a logistical necessity will be available in and around the lodging facility, is critical to the successful performance of the Veterans' Health Study and to the credibility of the Lovelace Medical Foundation, a research organization. This objective may be accomplished through enforcement of applicable Lovelace/lodging facility agreements. Enforcement is the responsibility of the Deputy Project Director.

- (1) Under such agreements, the lodging facility management will:
 - (a) Ensure that employees in certain specified positions receive the CDC briefing on "The Assurance of the Confidentiality of Participant Data," and that they acknowledge in writing the penalty for violation of this requirement.
 - (b) In addition, the hotel management agrees to reinforce the importance and seriousness of the Assurance of Confidentiality requirement through adequate training and follow-up with its employees. Such training will be verified by the Deputy Project Director.
 - (c) Register study participants for the Lovelace Medical Foundation account only by name and participant identification number, without requiring participants to furnish home addresses or other identifying data.

- (d) Maintain under lock and key, when not in use, all records which identify any guests as study participants; restrict the use of such records to authorized employees.
 - (e) Ensure that no information related to study participants, or data collected through their examinations, will be released or publicized without the prior written permission of the Lovelace Medical Foundation.
 - (f) Purge from their records, all data pertaining to the names of study participants such that, at the conclusion of the Lovelace/lodging facility business relationship or the Veterans' Health Study, whichever occurs first, no identifiable record of any participant's stay (as a study participant) will exist.
 - (g) As specified by Lovelace, return to Lovelace or the Centers for Disease Control or destroy, all information which in any manner identifies hotel guests as study participants.
- k. Enforcement of the above stated provisions will be accomplished by the Deputy Project Director using methods such as the following:
- (1) Periodic monitoring of Assurance of Confidentiality statements signed by hotel employees. This will require routine checking with the hotel management to ensure that new employees in the specified positions are receiving the confidentiality briefing and acknowledging it in writing as required.
 - (2) Providing assistance to hotel management as necessary to support the required training and associated follow-up of their employees.
 - (3) Ensure that participants are routinely informed, prior to their arrival, that they should not provide the hotel with information other than their names; ensure that participants are informed on how to establish private charge accounts with the hotel, and are also informed that such accounts cannot link the participant directly to his study participation, but will link him to the hotel and to his presence in Albuquerque.
 - (4) Periodically inspect the hotel's guest records maintenance methods.

1. Logistics Management Contact With Lodging Facility Personnel

The lodging facility is a private organization conducting business with the Lovelace Medical Foundation. Its personnel in no way report to or are subject to the direction of Lovelace Medical Center personnel. However, assuming that the management of both the Lovelace Medical Foundation and the lodging facility have an interest in the successful and effective conduct of the Veterans' Health Study, the following rules must be agreed upon and supported by both organizations:

- (1) The Lovelace Veterans' Health Study Project Director and Deputy Project Director will identify, become acquainted with and maintain effective communications with at least one key management employee in each hotel operation having a direct effect on study effectiveness. Such areas of hotel operation include, but are not limited to, General Management, Registration Desk, Billing and Collections and Guest Services.
- (2) It is necessary that the lodging facility recognize and respond to requests made by Lovelace Medical Foundation personnel, who have been identified to the lodging facility management as representing Veterans' Health Study management. Such personnel include, but are not limited, to Participant Advocates and the Senior Scheduler. Any request perceived as unreasonable by hotel staff or management should be confirmed with the Veterans' Health Study Project Director or Deputy Project Director before it is refused.
- (3) To ensure ongoing effective communication, it is suggested that meetings at a minimum of once a month be held to discuss and resolve problem areas. These meetings will include the following individuals:
 - (a) Veterans' Health Study Logistics Manager
 - (b) The available Participant Advocate
 - (c) The hotel Guest Services Manager
 - (d) The hotel Front Desk Manager.

m. Equipment and Supplies

All equipment and supplies necessary to the lodging of study participants will be provided by the hotel.

n. Problem Procedures

The purpose of the following procedures is to effectively solve or handle problems which may arise from the lodging of study participants.

(1) Participant Emergencies:

(a) Medical or Psychological

- (i) The hotel management will ensure that knowledge of any study participant experiencing a medical or psychological problem will be revealed to an employee in one of the following specified job positions, who will immediately report the emergency to the Lovelace Medical Center Emergency Center.

(b) Family

- (i) The hotel management will ensure that notification of a family emergency will be provided to a study participant by contacting him either in his hotel room or at the Lovelace clinic site. Both telephone numbers will be provided to study participants before they depart their homes for Albuquerque.

(2) Participant Problems:

The hotel management will immediately notify the Deputy Project Director and the assigned Participant Advocate should any study participant misbehave to a degree deemed to justify eviction or apprehension by the legal authorities. The Advocate will provide assistance as is appropriate and authorized

o. Quality Control

The quality of participant lodging and related services, as provided by agreements between the Lovelace Medical Foundation and the lodging facility, will be monitored and controlled by the following methods:

- (1) Observation by the Project Director and Deputy Project Director through site visits and inspections, as well as by the Participant Advocates, Medical Diagnosticians and Psychologists.
- (2) Feedback from participants to Participant Advocates and other study personnel.
- (3) Observation by the CDC Site Monitor through visits and inspections.
- (4) Data obtained from completed Participant Satisfaction Questionnaires.

6. Procedure for Providing Study Participants With Cash for Off-Site Dining and Entertainment

a. Objective

The objective of this procedure is to provide each study participant with cash so that he may decide for himself where and on what he wishes to dine. Included is the provision of an entertainment allowance for each participant.

b. Early Arrival/Late Departure

- (1) Participants who, AT LOVELACE'S CONVENIENCE, arrive in Albuquerque one (1) or more days prior to their block date, or who depart from Albuquerque one (1) or more days after the normal departure date for their block. To ensure that these participants receive money for meals on these days, the following will occur:
 - (a) Each Participant Advocate will review his/her participant lodging list prior to delivering it to the hotel. The Advocate will identify on the list, participants arriving one or more days early or departing one or more days late AT STUDY CONVENIENCE. IN RED INK, an amount of cash to be issued to the participant when he registers at the hotel will be indicated. For each day any participant is, at study convenience, arriving earlier than his Block Date, and for each day any participant is, at study convenience, to be held over after his Day Four, the participant is to receive \$25.00 cash.
 - (b) The hotel reservations staff will review the participant lodging list and identify any participants who are to receive cash upon registering. As any participant so identified registers for his hotel room, he will be issued, by hotel personnel, the amount of cash indicated by the Advocate.
 - (c) The hotel will bill Lovelace for the cash issued, along with the charge for the participant's room.
 - (d) The Deputy Project Director, upon receipt of each hotel bill, will check to ensure that any cash so issued matches extra days of study-required participant stay.
- (2) Participants whose early arrival on their Block Date or whose late departure on Day Four requires that they be provided lunch at Lovelace expense. Lunches will be provided to these participants as follows:

- (a) The responsible Advocate will decide which participants are to be provided lunch at study expense.
- (b) The Advocate will provide each such participant with a hotel restaurant authorization form which the Advocate will complete by filling in the participant's name and room number. Before giving it to the participant, the Advocate will sign and date the form. The Advocate will remind the participant that the lunch authorization DOES NOT INCLUDE ALCOHOLIC BEVERAGES.
- (c) Upon finishing his lunch, the participant will give his authorization form to the hotel coffee shop cashier who will verify that the form has been completed, signed and dated by a study Advocate.
- (d) The hotel will add the charge for the participant's authorized lunch(es) to the Lovelace bill for the participant's lodging.
- (e) Upon receipt of the hotel participant lodging bill, the Deputy Project Director will ensure that each lunch charged is accompanied by a properly completed authorization form.

c. Meals/Entertainment During Examination Period

- (1) Three (3) dinners.
- (2) One (1) breakfast.
- (3) Entertainment allowance.

d. Cash Provision

In the following, reference is made to "the cashier." "The cashier" will be the Office Participant Advocate, the study Administrative Specialist, or the Psychological Operations Secretary who works full-time at the hotel Study Satellite Office, as designated by the Deputy Project Director through the Logistics Manager.

- (1) Monday:
 - (a) The First National Bank will deliver to the lodging facility, a locked bag containing up to one hundred (100) envelopes. The number of envelopes delivered will depend on the number of envelopes left over from the previous week such that the total number of envelopes available equals one hundred (100).

- (b) The locked bag will be received by a designated member of the hotel staff who will deposit the bag in the hotel safe. Each envelope, as prepared and double-verified by the bank, will contain \$57.00 in cash (one fifty, one five and two ones).
 - (c) Prior to 3:00 P.M., the cashier will obtain and sign for the locked bag of envelopes from the hotel safe. He/she will verify the correct number of envelopes delivered and report any shortage to the Deputy Project Director. The cashier, using the key kept in his/her possession, will place the envelopes into the designated safety deposit box located in the room behind the hotel front desk.
 - (d) Between 3:00 P.M. and 4:00 P.M., the cashier will meet the Monday Participant Advocate at the hotel safety deposit box and issue to that Advocate, the number of envelopes which equals the number of participants expected at that day's orientation. The cashier will require the Advocate to sign for the number of envelopes received.
 - (e) During participant orientation, the Advocate will issue one envelope to each attending participant, requiring him to acknowledge receipt of his envelope in writing. The Advocate will inform all participants that the amount received is based on an allowance of \$12.00 for each of three (3) dinners, \$6.00 for one (1) breakfast and \$15.00 for entertainment the evening of Psychological Testing Day, when the alcohol restriction has been lifted.
 - (f) The Advocate will return any nonissued envelopes to the cashier by 3:00 P.M. the following day.
- (2) Tuesday: Between 3:00 P.M. and 4:00 P.M., the cashier will meet and issue envelopes to the Tuesday Participant Advocate as described for the Monday Advocate above. The Tuesday Advocate will issue, account for and return envelopes as described above.
- (3) Wednesday:
- (a) Between 10:00 A.M. and 12:00 Noon, the cashier will obtain the key to hotel safety deposit box from the Sunday Participant Advocate, count the number of envelopes, if any, remaining in the box and place into the box, the number of envelopes necessary to equal a total of twenty five (25). The cashier will return the key to the Sunday Advocate, who will acknowledge in writing his/her receipt of the envelopes just added by the cashier.

(b) Between 3:00 P.M. and 4:00 P.M., the cashier will meet and issue envelopes to the Wednesday Participant Advocate as described above. The Wednesday Advocate will issue, account for and return envelopes as described.

(4) Thursday:

(a) Between 3:00 P.M. and 4:00 P.M., the cashier will audit the hotel safety deposit box, count the number of envelopes remaining and account for that number of envelopes which, together with the number of envelopes remaining, equals one hundred (100).

(b) Between 4:00 P.M. and 4:30 P.M., the cashier will phone a designated member of the First National Bank's vault staff and order, for delivery the following Monday, the number of envelopes necessary to bring the number on hand up to one hundred (100). The cashier will report this order to the Logistics Manager by 10:00 A.M. the following day. The Logistics Manager will see that documentation of this order is provided in writing to the First National Bank, with a copy to the Lovelace Medical Center accounting department.

(5) Sunday: Between 3:00 P.M. and 4:00 P.M., the Sunday Advocate will obtain from the hotel safety deposit, enough envelopes so as to be able to issue one to each participant attending Sunday orientation. The Advocate will issue and account for envelopes as described above. The Advocate will return any nonissued envelopes to the safety deposit box prior to 10:00 A.M. the following Wednesday.

e. Auditing

(1) Each Friday, upon being informed of the number of envelopes ordered by the cashier for delivery the following Monday, the Logistics Manager will ensure that the number of envelopes ordered equals the number of participants who have arrived that week. Any discrepancies are to be researched by the Logistics Manager until total accounting has been accomplished.

(2) Periodically and at least semi-monthly, the Logistics Manager, or his designated representative, will audit the hotel safety deposit boxes to ensure that proper accounting for cash envelopes is taking place.

f. Contingency Planning

Certain Mondays during each year are holidays for the First National Bank. In such cases, delivery of cash envelopes will take place on Tuesday of the affected week. The cashier will be notified by the bank at least two weeks prior to any Monday bank holiday and then will, on Thursday prior to the Thursday before the Monday bank holiday, order and account for an extra twenty five envelopes for issuance to the Monday Advocate on the Monday of the bank holiday.

7. Protocol for Handling Phone Calls From Veterans' Health Study Participants

a. Participant Phones Lovelace From His Home

- (1) Participant phones during working hours (MST): Connect participant to the Veterans' Health Study Office.
- (2) Participant phones during evenings or weekends: Ask participant to call back during normal working hours.

b. Participant Phones While Enroute To/From Lovelace

- (1) Participant phones during working hours (MST)
 - (a) Participant requests general information or only wishes to leave a message: Connect participant to the Veterans' Health Study office.
 - (b) Participant needs travel assistance: Connect participant to AAA Travel Agent in the Veterans' Health Study office.

c. Participant Phones During Evenings or Weekends

- (1) Participant requests general information only: Request that participant wait until he arrives in Albuquerque to receive information, or that he phone the Veterans' Health Study office during working hours after he arrives back home.
- (2) Participant needs travel assistance: Ask participant to call the AAA Travel Assistance toll free number (1-800-TRIPLE A) or (1-800-874-7532); remind participant to tell the Triple A travel assistance people that he was booked in Albuquerque.

- (3) Participant only wishes to leave a message: Take participant's message and forward it to the hotel front desk.
- d. Friend or Relative of Participant Phones Participant While He Is in Albuquerque
 - (1) Friend or relative phones during working hours (MST). Connect call to Veterans' Health Study office.
 - (2) Friend or relative phones during evenings or weekends. Request that caller phone the hotel.
- e. Emergency Contact
 - (1) IF THE SITUATION CANNOT BE HANDLED BY THE ABOVE PROTOCOL, CONTACT THE VETERANS' HEALTH STUDY DEPUTY PROJECT DIRECTOR.
 - (2) During normal working hours - Veterans' Health Study Office (505-262-7600).

8. APPENDIX 1 - 12-Hour Urine Specimen Collection Instructions

You have been provided with the proper container and equipment for a 12-hour urine collection. Please follow these instructions to guarantee an accurate specimen collection:

The white powder in your urine collection container is a preservative (sodium carbonate). LEAVE IT IN THE CONTAINER; DO NOT TOUCH IT.

- (1) At exactly 7:00 o'clock p.m., urinate into the TOILET. Do this even if you do not feel like you have to or if you went only a short time before. Please write the date and time on the container label after the word "START."
- (2) After this and up until 7:00 o'clock in the morning, EVERY TIME YOU HAVE TO URINATE, do it in the container provided.
- (3) Each time you urinate in the container, please remove the container from the ice chest first. Also, IT IS VERY IMPORTANT THAT YOU REPLACE THE CONTAINER LID AND PUT THE CONTAINER BACK INTO THE ICE CHEST BETWEEN THE TWO ICE PACKS AFTER EACH TIME YOU URINATE.
- (4) At exactly 7:00 o'clock in the morning, urinate into the specimen container even if you do not feel like it or if you went only a short time before. Please write the date and time on the container label after the word "END."
- (5) Replace the lid to the urine container TIGHTLY PLEASE, return the container to the ice chest between the ice packs and take the ice chest with you when you meet your Advocate in the hotel lobby in the morning.

SPECIAL TIPS:

TO KEEP FROM FORGETTING TO USE YOUR URINE COLLECTION CONTAINER, IT IS A GOOD IDEA TO KEEP IT SITTING ON THE TOILET SEAT IN YOUR HOTEL BATHROOM.

IT IS OKAY TO DRINK A MEDIUM AMOUNT OF WATER DURING THE URINE COLLECTION PERIOD.

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MEDICAL RECORDS MANUAL

VI. Logistics and Medical Records Manuals

B. Medical Records

1. Introduction

- a. The hardcopy medical record will be stored in a lockable file room and will remain in this area except for review by the Diagnostician and for results interview. Examiners will not have access to the paper documents.
- b. The hardcopy medical record will only be on site at Lovelace Medical Center for a period of 30 days, at which time it will be forwarded to CDC.

2. Supplies

The hardcopy medical record will consist of a green/gray 25 pt QPB shell file folder, letter size with right exposure with fastener #1 and #3 position, 2 inch prongs. There are four dividers on the inside. Green for medical, blue for psychological, yellow for laboratory, and pink for tests. The medical and psychological exams will be filed on the left side when opening the medical record, laboratory and tests will be filed on the right side when opening the medical record.

3. Procedures

- a. The participant schedule report will be printed on Friday for the following week. This will include a medical testing schedule for the day of the physical examination (see Section 10). A copy of the report will be distributed to the Medical Records manager. The day prior to the arrival of a block of participants, a new list will be made with additions, deletions and changes if necessary. On Friday, when the report is received, the Medical Records clerk will make all Medical Records and x-ray jackets ready with participant names and assigned numbers, for use the following week. If necessary, Saturday will also be used for this function.
- b. The clerk will make sure that all consent forms are received. If any consent forms are missing, the clerk will give these names to the participant advocate responsible for that specific block. The advocate will assure the completion and collection of the consent form before starting any test or exam.
- c. A nurse at the nurses' station will bring all tests and examinations received for that day to the Medical Records

clerk. The Medical Records clerk will check each test to ensure all tests are complete and signed. The tests to be filed directly on the medical record are:

- (1) Nerve conduction velocities
- (2) Quantitative peripheral sensory I
- (3) Quantitative peripheral sensory II
- (4) Chest X-Ray
- (5) Dermatology examination
- (6) Neurology examination
- (7) Physical examination

- d. The ECG and pulmonary function test will be taken to the cardiology and pulmonary clinic for interpretation by cardiology and pulmonary physicians, respectively. As soon as this task is completed, the Medical Records clerk will retrieve these tests from the clinics. The Medical Records clerk will check the tests for completion. The Medical Records clerk will take ECG, pulmonary function tests, audiograms, and visual acuity exams to Data Entry. Once a day a cardiologist will interpret all Doppler exams in the Medical Records department.
- e. Should the Medical Records clerk discover deficiencies, the deficient test will be returned to the person responsible for correction. The report will be logged out to the person responsible for correction and logged in when returned, corrected, to the Medical Records department.
- f. To ensure confidentiality and security, the Medical Records department doors will be locked when personnel are not present, in which case hardcopies will be delivered to the clinical manager's office.
- g. Medical records personnel will maintain check-off lists to assure all tests and exams required in the department and medical record are completed. These check-off lists will be maintained for construction of the medical record until shipment to CDC.
- h. Each medical history will be obtained by a physician assistant. Upon completion and review, the hardcopy will be delivered to the Medical Records department. The Medical Records technician will check the history for deficiencies; if present, the history will be returned to the person responsible for correction. The history will be logged out to the Physician Assistant and logged back in after correction.
- i. The Medical Records technician will assign ICD-9-CM drug and occupational codes where appropriate, and deliver the history hardcopy to the data entry department.

- j. A data entry specialist will use the history hardcopy for their assigned function, and will return it to the Medical Records department where it will be filed on the medical record.
- k. The Medical Records clerk will make a list as to which physician did a general physical examination on which participant. This list will be forwarded to the participant advocate in order to assure that a diagnostician will not read or interview a participant on which he/she did an examination.
- l. Laboratory test results on blood and urine specimens will be picked up by the Medical Records clerk at 5:00 p.m. on Day 3. These laboratory tests will be filed immediately on the medical record.
- m. Incomplete findings will be specially marked off on the check-off list. If available, late findings will be placed on the medical record and the receiving diagnostician (reader) will be notified about the delayed report so it can be reviewed when the Medical Records clerk delivers the record to the review room.
- n. The participant advocate will read and enter the results of the hypersensitivity test on the designated form placed on the medical record during the results interview at the lodging facility.
- o. Any information not available at results interview time, whether due to technical problems with the computers or other unforeseen reasons will be reported to the participant by mail.
- p. On Day 3 the head neuropsychology technician will take all tests, sorted by participant, to the Medical Records department. These will be filed in the individual participant's medical record.
- q. The record will be delivered to the first reviewing diagnostician at 5:00 p.m. Upon completion of the first review, the Medical Records clerk will claim the Medical Records.
- r. The Medical Records clerk will box all Medical Records needed for results interview at the lodging facility on Day 4.
- s. The participant advocate accompanying the records to the lodging facility for results interview must accompany their return to the Lovelace records clerk for final processing.
- t. The Medical Records technician will check the records for deficiencies on their return from the results interview. Deficiencies found will be marked on a deficiency form used only for the final check purpose. The copy will be filed by date and checked every Friday against the record to ensure that deficiencies have been corrected. The person(s) responsible for

deficiencies will be called and asked to make corrections in the medical records department. THE MEDICAL RECORD WILL NOT LEAVE THE DEPARTMENT FOR ANY REASON EXCEPT SCHEDULED REVIEW BY DIAGNOSTICIANS AND RESULTS INTERVIEW.

- u. After return of all Medical Records from the lodging facility, the results interview form will be coded (ICD-9-CM) for diagnosis, taken off the record and delivered to data entry by the Medical Records technician.
- v. The hypersensitivity tests filled out by participant advocates will be checked for completion and taken to Data Entry.
- w. Data entry will return the results interview form and hypersensitivity test to Medical Records for placement on the record. The Medical Records specialist or technician will check the record for:
 - (1) Release of partial or entire medical record to a participant's medical care provider (see Sections 11 and 12).
 - (2) Follow-up medical care advised to participants with serious conditions (see Section 13).
- x. The Medical Records and x-ray films will be filed according to the terminal digit filing system.

4. Supervision

The Medical Records department is supervised by the Medical Records specialist who, in turn, is supervised by the Deputy Project Director.

5. Quality Control

- a. To meet the objectives of the quality control program, the hardcopy medical record will be monitored continuously during the examination process. Results will be filed throughout the day by the Medical Records staff who will log in each component as it is received and processed. This ongoing review will allow immediate identification of missing exam/test results. In conjunction with the participant advocates and the clinical staff, the Medical Records staff will locate the missing data and assure its placement in the medical record. Reports will be maintained of these occurrences for review by Project Management.

- b. Prior to being forwarded to the Diagnosticians for review and results interview, a final medical record review will be done by Medical Records staff. This will assure that complete records are available for this final component of the examination process.
- c. Weekly quality control checks will be performed on all reports filed in the medical record. The Medical Records specialist will randomly select 10% of the reports received for filing on a given day and record the participant's name and type of report. The following day, the specialist will compare the list with the actual medical record to ascertain the accuracy rate. Should errors be found, the filing staff will be counseled.
- d. A report of these errors will be sent at week's end to the Veterans' Health Study Program Director.
- e. The Medical Records specialist will do a random 10% quality check on Medical Records to ensure the record has been constructed and completed correctly. The 10% will be chosen by taking every ninth (9th) medical record number from the daily participant census report.

6. Backup

a. Medical Records Technician

The Medical Records technician will, when needed, be assisted by the Medical Records specialist in all functions.

b. Medical Records Clerk

(1) The Medical Records clerk will, when needed, be assisted by the Medical Records technician and the Medical Records specialist.

(2) Additional backup is available from the Lovelace Medical Records Department.

7. Training

a. Medical Records Technician

The Medical Records technician will be trained by the Medical Records specialist to meet specific coding and information flow requirements of the Veterans' Health Study. The Medical Records technician will be trained by the Medical Records specialist in performing quality checks on the medical record and to be a backup for the Medical Records clerk.

b. Medical Records Clerk

The Medical Records clerk will be trained by the Medical Records specialist in the proper flow and filing of reports, tests and laboratory results to achieve a perfect construction of the medical record.

8. Policy and Protocol for Release of Confidential Medical Examination Results to Individual Participants or Their Designated Surrogates

There will be times when participants of the medical/psychological component of the Veterans' Health Study will want copies of their individual medical record. Individual study participants and their designated surrogates (generally, medical care providers) will continue to have access to individual Medical Records indefinitely into the future. A strict protocol is designed to ensure that information is kept confidential and is protected from release to anyone other than the particular participant or his designated surrogate. At the same time, it is the intent of Lovelace to afford ready access to individual medical results to the particular study participant. The following protocol shall be, in effect, to handle the release of medical information requested after the participant has returned home.

a. Medical record information will be released after receipt of a signed "medical record release form." There are five (5) possible ways for release of the medical record in full or part:

- (1) A signed release for the entire medical record.
- (2) A signed release for the psychological exam only.
- (3) A signed release for the medical exam only.
- (4) A signed release for tests and/or laboratory results as specified by participant.
- (5) A signed release for other parts of the medical record specifically requested by participant. Example: neurological only; urinalysis only; dermatology exam only; or any combination possible.

b. Telephone inquiries from alleged participants or providers of medical care will not be honored.

c. Signatures must be either notarized or consciously matched with signatures on file in the particular record.

d. If records are to be sent to an address other than the "address of record" where the participant was residing when he was first contacted by Lovelace/CDC study staff, then a notarized signature on the medical record release form will be required.

- e. To ensure medical record information will be sent to certified medical care providers, the participant will sign the appropriate Medical Records release form.
 - f. In each individual case, the Medical Records specialist will research the name, address and certification of the medical care provider in The Directory of Physicians in the U.S., Puerto Rico, Virgin Islands, certain Pacific islands and U.S. physicians temporarily located in foreign countries to whom the records are to be sent.
 - g. Only the Medical Records specialist shall have the authority to release confidential information. The original signed form will become part of the permanent medical record.
 - h. Copies of requested Medical Records will be sent within seven (7) working days following receipt of a qualified request.
 - i. Lovelace Medical Foundation will have possession of the permanent medical record of an individual participant for only 30 days following completion of the medical examination. All requests received after the sole copy of the permanent medical record has been transferred to the CDC shall be forwarded with the original medical release form (by certified mail) to the CDC Study Medical Director or his/her designate within seven (7) working days of receipt.
 - j. Any problems or discrepancies will be brought to the attention of the Lovelace program director and, if unresolvable, will be brought to the attention of the CDC study directors.
 - k. A cover letter will accompany any and each part or entire medical record released to a medical care provider.
9. Policy and Protocol for Follow-Up for Serious Medical Problems

There will be times when examiners of the medical examination component of the Veterans' Health Study will discover a serious and/or terminal medical problem in a participant which requires prompt medical attention and/or follow-up. The following is the policy and protocol to ensure the highest level of follow-up by the participant after he has returned home.

- a. Participants with serious and/or terminal medical problems to whom the results are not disclosed because it is in the best interest of the participant: If these participants indicate at the time of debriefing that they do not have a personal health provider, the following policy applies. The Medical Records specialist will make a card with name and address on this participant. Every fifteen (15) days these cards shall be

reviewed to ensure that a release for medical information was received by us. If, in thirty (30) days, no medical record transfer request is received, the Medical Records specialist shall advise the Veterans' Health Study Medical Director of the situation. The Medical Director shall follow up (see Section 13).

10. Medical Testing Schedule

| (Time) | Participant Number | | | | | | | | | | | |
|--------|--------------------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 |
| 8:00am | LAB | LAB | LAB | SUBQ | PF | NCV | HISTORY | XRAY | ----- | QPS1 | QPS2 | ----- |
| 8:10 | ECG | ECG | ECG | FF | ----- | NCV | HISTORY | XRAY | SUBQ | QPS1 | QPS2 | SUBQ |
| 8:20 | XRAY | SUBQ | SUBQ | LAB | LAB | NCV | HISTORY | LAB | ECG | OPS2 | QPS1 | DOP |
| 8:30 | XRAY | NCV | HISTORY | ECG | ECG | ECG | SUBQ | DOP | ----- | OPS2 | QPS1 | ----- |
| 8:40 | BKFST | NCV | HISTORY | BKFST | BKFST | LAB | LAB | PF | AUDIO | SUBQ | LAB | ----- |
| 8:50 | BKFST | NCV | HISTORY | BKFST | BKFST | BKFST | DOP | ECG | AUDIO | LAB | ECG | PF |
| 9:00 | BKFST | BKFST | BKFST | BKFST | BKFST | BKFST | ECG | BKFST | LAB | ----- | BKFST | LAB |
| 9:10 | HISTORY | BKFST | BKFST | NCV | XRAY | BKFST | BKFST | BKFST | BKFST | ECG | BKFST | ECG |
| 9:20 | HISTORY | BKFST | BKFST | NCV | XRAY | AUDIO | BKFST | BKFST | BKFST | BKFST | BKFST | BKFST |
| 9:30 | HISTORY | QPS1 | QPS2 | NCV | DOP | AUDIO | BKFST | SUBQ | BKFST | BKFST | PF | BKFST |
| 9:40 | PF | QPS1 | QPS2 | DOP | NCV | ----- | NCV | AUDIO | HISTORY | BKFST | ----- | BKFST |
| 9:50 | DOP | QPS2 | QPS1 | XRAY | NCV | ----- | NCV | AUDIO | HISTORY | ----- | ----- | ----- |
| 10:00 | SUBQ | QPS2 | QPS1 | XRAY | NCV | DOP | NCV | ----- | HISTORY | PF | ----- | ----- |
| 10:10 | QPS1 | PF | XRAY | QPS2 | ----- | ----- | ----- | NCV | ----- | HISTORY | DOP | ----- |
| 10:20 | QPS1 | DOP | XRAY | QPS2 | SUBQ | SUBQ | ----- | NCV | ----- | HISTORY | ----- | ----- |
| 10:30 | QPS2 | XRAY | DOP | QPS1 | ----- | ----- | ----- | NCV | PF | HISTORY | SUBQ | ----- |
| 10:40 | QPS2 | XRAY | PF | QPS1 | LAB 2/UA | LAB 2/UA | ----- | ----- | ----- | ----- | ----- | ----- |
| 10:50 | NCV | HISTORY | NCV | HISTORY | ----- | ----- | ----- | LAB 2/UA | LAB 2/UA | LAB 2/UA | ----- | ----- |
| 11:00 | NCV | HISTORY | NCV | HISTORY | QPS1 | ----- | PF | ----- | QPS2 | ----- | LAB 2/UA | LAB 2/UA |
| 11:10 | NCV | HISTORY | NCV | HISTORY | QPS1 | ----- | XRAY | ----- | QPS2 | DOP | ----- | ----- |
| 11:20 | LAB 2/UA | LAB 2/UA | LAB 2/UA | ----- | QPS2 | PF | XRAY | ----- | QPS1 | ----- | ----- | AUDIO |
| 11:30 | LNCH | LNCH | LNCH | LAB 2/UA | QPS2 | LUNCH | LAB 2/UA | LNCH | QPS1 | LNCH | LUNCH | AUDIO |
| 11:40 | LNCH | LNCH | LNCH | LNCH | LNCH | LUNCH | LNCH | LNCH | DOP | LNCH | LUNCH | LUNCH |
| 11:50 | LNCH | LNCH | LNCH | LNCH | LNCH | LUNCH | LNCH | LNCH | LUNCH | LNCH | LUNCH | LUNCH |
| NOON | LNCH | LNCH | LNCH | LNCH | LNCH | LUNCH | LNCH | LNCH | LUNCH | LNCH | LUNCH | LUNCH |
| 12:10 | LUNCH | LUNCH | LUNCH | LUNCH | LUNCH | LUNCH | LUNCH | LUNCH | LUNCH | LUNCH | LUNCH | LUNCH |
| 12:20 | VITALS | VITALS | ----- | LNCH | LNCH | ----- | LUNCH | ----- | LNCH | ----- | ----- | LUNCH |
| 12:30 | PHYS | PHYS | NEURO | NEURO | ----- | ----- | VISION | QPS1 | LNCH | ----- | ----- | ----- |
| 12:40 | PHYS | PHYS | NEURO | NEURO | HISTORY | HISTORY | AUDIO | QPS1 | XRAY | ----- | NCV | NCV |
| 12:50 | DERM | ----- | NEURO | NEURO | HISTORY | HISTORY | AUDIO | QPS2 | XRAY | ----- | NCV | NCV |
| 1:00 | AUDIO | DERM | VITALS | VITALS | HISTORY | HISTORY | NEURO | QPS2 | ----- | XRAY | NCV | NCV |
| 1:10 | AUDIO | ----- | PHYS | PHYS | ----- | ----- | NEURO | HISTORY | ----- | XRAY | HISTORY | ----- |
| 1:20 | ----- | ----- | PHYS | PHYS | VITALS | VITALS | NEURO | HISTORY | ----- | ----- | HISTORY | XRAY |
| 1:30 | NEURO | NEURO | DERM | ----- | PHYS | PHYS | ----- | HISTORY | ----- | VISION | HISTORY | XRAY |
| 1:40 | NEURO | NEURO | ----- | DERM | PHYS | PHYS | ----- | ----- | VITALS | AUDIO | ----- | VISION |
| 1:50 | NEURO | NEURO | VISION | ----- | DERM | ----- | ----- | ----- | PHYS | AUDIO | ----- | ----- |
| 2:00 | VISION | ----- | AUDIO | ----- | NEURO | DERM | ----- | VITALS | PHYS | ----- | VITALS | ----- |

| | | | | | | | | | | | |
|------|--------|--------|--------|--------|------|--------|--------|--------|-------|--------|---------|
| 2:10 | VISION | AUDIO | ---- | NEURO | ---- | | PHYS | NCV | DERM | PHYS | ---- |
| 2:20 | AUDIO | | ---- | NEURO | QPS1 | VITALS | PHYS | NCV | ---- | PHYS | QPS2 |
| 2:30 | AUDIO | | ---- | ---- | QPS1 | PHYS | NEURO | NCV | ---- | VISION | QPS2 |
| 2:40 | | AUDIO | ---- | ---- | QPS2 | PHYS | NEURO | ---- | NCV | ---- | QPS1 |
| 2:50 | | AUDIO | VISION | QPS2 | DERM | NEURO | NEURO | ---- | NCV | ---- | QPS1 |
| 3:00 | | VISION | AUDIO | ---- | QPS1 | ---- | NEURO | NCV | NEURO | NEURO | HISTORY |
| 3:10 | | | AUDIO | NEURO | QPS1 | ---- | NEURO | ---- | NEURO | NEURO | HISTORY |
| 3:20 | | | | NEURO | QPS2 | ---- | NEURO | ---- | NEURO | NEURO | HISTORY |
| 3:30 | | | | NEURO | QPS2 | DERM | ---- | NEURO | ---- | ---- | ---- |
| 3:40 | | | | XRAY | | ---- | ---- | NEURO | DERM | NEURO | NEURO |
| 3:50 | | | | XRAY | | ---- | VISION | NEURO | ---- | NEURO | NEURO |
| 4:00 | | | | VISION | | ---- | ---- | ---- | ---- | XRAY | NEURO |
| 4:10 | | | | | | VISION | ---- | VITALS | XRAY | PHYS | VITALS |
| 4:20 | | | | | | | | PHYS | AUDIO | PHYS | PHYS |
| 4:30 | | | | | | | DERM | PHYS | AUDIO | PHYS | PHYS |
| 4:40 | | | | | | | | | | DERM | DERM |
| 4:50 | | | | | | | | | | | |
| 5:00 | | | | | | | | | | | |

10. Medical Testing Schedule (continued)

| (Time) | Participant Number | | | | | | | | | | |
|--------|--------------------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|
| | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | 22 | 23 |
| 8:00am | QPS2 | QPS1 | ----- | AUDIO | HISTORY | NCV | DOP | SUBQ | ECG | ECG | ECG |
| 8:10 | QPS2 | QPS1 | DOP | AUDIO | HISTORY | NCV | ----- | ----- | LAB | LAB | LAB |
| 8:20 | QPS1 | QPS2 | PF | ECG | HISTORY | NCV | ECG | ----- | ----- | ----- | AUDIO |
| 8:30 | QPS1 | QPS2 | ----- | PF | SUBQ | LAB | LAB | LAB | HISTORY | NCV | AUDIO |
| 8:40 | SUBQ | XRAY | ----- | DOP | ECG | ECG | BKFST | ECG | HISTORY | NCV | BKFST |
| 8:50 | ECG | XRAY | ----- | LAB | LAB | ----- | BKFST | BKFST | HISTORY | NCV | BKFST |
| 9:00 | PF | ECG | ECG | BKFST | AUDIO | DOP | BKFST | BKFST | BKFST | BKFST | BKFST |
| 9:10 | LAB | LAB | LAB | BKFST | AUDIO | BKFST | NCV | BKFST | BKFST | BKFST | HISTORY |
| 9:20 | BKFST | PF | BKFST | BKFST | BKFST | BKFST | NCV | DOP | BKFST | BKFST | HISTORY |
| 9:30 | BKFST | BKFST | BKFST | SUBQ | BKFST | BKFST | NCV | XRAY | QPS1 | QPS2 | HISTORY |
| 9:40 | BKFST | BKFST | BKFST | HISTORY | BKFST | ----- | SUBQ | XRAY | QPS1 | QPS2 | SUBQ |
| 9:50 | ----- | BKFST | SUBQ | HISTORY | ----- | ----- | ----- | ----- | QPS2 | QPS1 | PF |
| 10:00 | AUDIO | ----- | ----- | HISTORY | ----- | SUBQ | ----- | ----- | QPS2 | QPS1 | ----- |
| 10:10 | AUDIO | ----- | QPS1 | ----- | QPS2 | ----- | ----- | HISTORY | SUBQ | SUBQ | NCV |
| 10:20 | ----- | ----- | QPS1 | DOP | QPS2 | AUDIO | ----- | HISTORY | ----- | PF | NCV |
| 10:30 | ----- | SUBQ | QPS2 | ----- | QPS1 | AUDIO | ----- | HISTORY | ----- | ----- | NCV |
| 10:40 | ----- | ----- | QPS2 | ----- | QPS1 | LAB 2/UA | ----- | AUDIO | ----- | DOP | ----- |
| 10:50 | ----- | ----- | ----- | ----- | ----- | ----- | XRAY | AUDIO | PF | ----- | DOP |
| 11:00 | LAB 2/UA | AUDIO | ----- | ----- | ----- | QPS1 | XRAY | ----- | DOP | ----- | QPS2 |
| 11:10 | ----- | AUDIO | LAB 2/UA | ----- | ----- | QPS1 | LAB 2/UA | PF | ----- | LAB 2/UA | QPS2 |
| 11:20 | DOP | ----- | ----- | ----- | ----- | QPS2 | HISTORY | NCV | NCV | HISTORY | QPS1 |
| 11:30 | LUNCH | DOP | ----- | XRAY | PF | QPS2 | HISTORY | NCV | NCV | HISTORY | QPS1 |
| 11:40 | LUNCH | LAB 2/UA | AUDIO | XRAY | LAB 2/UA | PF | HISTORY | NCV | NCV | HISTORY | LAB 2/UA |
| 11:50 | LUNCH | LNCH | AUDIO | LAB 2/UA | DOP | LUNCH | PF | LAB 2/UA | LAB 2/UA | LNCH | LNCH |
| NOON | LUNCH | LNCH | LUNCH | LNCH |
| 12:10 | LUNCH | LUNCH | LUNCH | LUNCH | LUNCH | LUNCH | LUNCH | LUNCH | LUNCH | LUNCH | LUNCH |
| 12:20 | ----- | LNCH | LUNCH | LNCH | LUNCH | LNCH | LNCH | LNCH | LUNCH | LNCH | LNCH |
| 12:30 | ----- | LUNCH | LUNCH | LNCH | LUNCH | LNCH | LNCH | LNCH | LNCH | LNCH | LNCH |
| 12:40 | ----- | VISION | LUNCH | LUNCH | LNCH | NEURO | LNCH | LNCH | LNCH | VITALS | VITALS |
| 12:50 | ----- | ----- | ----- | VISION | ----- | NEURO | ----- | QPS1 | ----- | PHYS | PHYS |
| 1:00 | VISION | ----- | ----- | ----- | ----- | NEURO | ----- | QPS1 | NEURO | PHYS | PHYS |
| 1:10 | NCV | NCV | VISION | QPS1 | ----- | ----- | NEURO | QPS2 | NEURO | DERM | ----- |
| 1:20 | NCV | NCV | ----- | QPS1 | VISION | ----- | NEURO | QPS2 | NEURO | AUDIO | DERM |
| 1:30 | NCV | NCV | ----- | QPS2 | ----- | ----- | NEURO | ----- | ----- | ----- | ----- |
| 1:40 | ----- | HISTORY | NCV | QPS2 | NCV | HISTORY | QPS1 | NEURO | VITALS | ----- | XRAY |
| 1:50 | ----- | HISTORY | NCV | ----- | NCV | HISTORY | QPS1 | NEURO | PHYS | ----- | XRAY |
| 2:00 | ----- | HISTORY | NCV | ----- | NCV | HISTORY | QPS2 | NEURO | PHYS | XRAY | NEURO |

| | | | | | | | | | | | |
|------|---------|--------|---------|--------|--------|--------|--------|--------|--------|--------|--------|
| 2:10 | HISTORY | NEURO | HISTORY | NCV | ----- | ----- | QPS2 | ----- | ----- | XRAY | NEURO |
| 2:20 | HISTORY | NEURO | HISTORY | NCV | XRAY | DERM | VITALS | ----- | VISION | ----- | NEURO |
| 2:30 | HISTORY | NEURO | HISTORY | NCV | XRAY | ----- | PHYS | DERM | ----- | NEURO | ----- |
| 2:40 | NEURO | ----- | ----- | VITALS | DERM | VITALS | PHYS | ----- | XRAY | NEURO | VISION |
| 2:50 | NEURO | ----- | ----- | PHYS | ----- | PHYS | ----- | ----- | XRAY | NEURO | VISION |
| 3:00 | NEURO | ----- | XRAY | PHYS | VITALS | PHYS | DERM | VITALS | ----- | NEURO | ----- |
| 3:10 | ----- | ----- | XRAY | ----- | PHYS | VISION | ----- | PHYS | DERM | ----- | ----- |
| 3:20 | ----- | VITALS | VITALS | DERM | PHYS | XRAY | AUDIO | PHYS | ----- | VISION | ----- |
| 3:30 | ----- | PHYS | PHYS | NEURO | ----- | XRAY | AUDIO | VISION | ----- | ----- | ----- |
| 3:40 | VITALS | PHYS | PHYS | NEURO | ----- | ----- | VISION | ----- | ----- | ----- | ----- |
| 3:50 | PHYS | DERM | ----- | NEURO | ----- | ----- | ----- | ----- | AUDIO | ----- | ----- |
| 4:00 | PHYS | ----- | DERM | ----- | ----- | ----- | ----- | ----- | AUDIO | ----- | ----- |
| 4:10 | DERM | ----- | NEURO | ----- | NEURO | ----- | ----- | ----- | ----- | ----- | ----- |
| 4:20 | XRAY | ----- | NEURO | ----- | NEURO | ----- | ----- | ----- | ----- | ----- | ----- |
| 4:30 | XRAY | ----- | NEURO | ----- | NEURO | ----- | ----- | ----- | ----- | ----- | ----- |
| 4:40 | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- |
| 4:50 | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- |
| 5:00 | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- |

11. Letter About Delayed Results

Date:

To:

Recently, you underwent a battery of tests at Lovelace Medical Foundation for the Centers for Disease Control.

We informed you at that time that the results of some tests were not available at the time of your results interview, due to technical problems.

The results of those tests are now available and are as follows:

Sincerely,

William I. Christensen, M.D.
Medical Director
CDC Study

12. Letter About Release of Medical or Other Information

Date:

To:

This information has been disclosed to you from records whose confidentiality is protected by federal law. This prohibits you from making further disclosure without the specific written consent of the person to whom it pertains, or as otherwise permitted by such regulation.

A general authorization for release of medical or other information is NOT sufficient. Any reproduction of this information is prohibited.

Thank you for your cooperation.

Sincerely,

Elisabeth Elliott
Medical Records Specialist
Lovelace Veterans Health Study

13. Letter Concerning Follow-Up Care

Date:

To:

Your patient _____ recently participated in a study for the Centers for Disease Control in which he underwent a battery of laboratory tests, medical and physical examinations.

During these tests and examinations, the participant was diagnosed with a serious illness of which the severity was not disclosed to the participant because of lack of mental support from family or friends.

We are asking you, with the help of attached copied medical record, to inform your patient of his illness.

If you have any questions, do not hesitate to contact me.

Sincerely yours,

William I. Christensen, M.D.
Medical Director

Attachments

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VII. Data Management Manual

A. General Overview

1. Goal

The data management systems designed for this project are concerned with collection and reporting of accurate and complete examination data. A combination of key entry, optical scanning and data-entry systems and procedures has been constructed to support this goal.

2. Personnel Training

The Data Manager is responsible for developing, implementing and documenting training programs for all of the data management aspects of the Veterans' Health Study. Training concentrates on the principal areas of equipment and data collection, and is accomplished by both group and individual sessions.

3. Data Collection Procedures

a. Collection Methods

Data is collected through several methods: 100% verification key entry, optical scanning and computerized scoring data entry.

(1) Key entry

(a) One hundred percent (100%) verification keypunch is the method of data collection used in the following areas:

Medical History
General Physical
Neurological
Dermatological
Radiological
Peripheral Vascular
Nerve Conduction Velocity
Quantitative Peripheral Sensory I (Vibratron)
Quantitative Peripheral Sensory II (Thermal)
Electrocardiogram
Pulmonary Function
Hypersensitivity Skin Test (CMI)
Audiometry
Visual Acuity (Scores)
Word List (Scores)
Grooved Pegboard
Wide Range Achievement Test - 2
Modified Edinburgh Handedness Inventory
Results Interview Validity (Psych) Individual
Birth Facts
Locator Information

Results Interview Validity (Psych) Group
Locator Information
Diagnostic Interview Schedule

(b) Results of the tests and/or Birth Facts examinations are recorded on paper documents. Once the documents have been reviewed for accuracy and legibility, they are forwarded to the Medical Records Department to be filed in the participant's chart. Upon completion of the Results Interview, the documents are forwarded to Data Processing where they are again reviewed and prepared for entry by TBS data entry operators. If a document is found to be incomplete during any of these steps, it is immediately returned to the Lead Neuropsychology Technician or the Clinic Manager for completion. Exception to this procedure is the California Verbal Learning Tests (CVLT) which is keyed and scored with a commercial scoring package.

(2) Optical Scanning

(a) Optical scanning is utilized on seven of the psychological tests. Specially designed data forms have been developed that allow scanning to be accomplished.

The tests that are scanned are:

Army Classification Battery
Combat Exposure Index
Wechsler Adult Intelligence Scale
Delayed Rey-Osterrieth
Paced Auditory Serial Addition Test
Wisconsin Card Sort
Minnesota Multiphasic Personality Inventory

(b) The technician, or participant in the case of self-administered tests, completes the OCR testing forms. Periodically throughout the day various exams are forwarded to Data Processing. Data Processing personnel review the forms for completeness and prepare them in batches. If a form is incomplete and cannot be corrected by Data Processing, the Lead Neuropsychology Technician is contacted for instructions. The forms are then scanned using National Computer Systems Sentry 3000, interfaced to an IBM PC/XT. A commercial scoring program is utilized for the MMPI. The other tests are scored with programs written by Lovelace personnel.

(3) Laboratory Data

(a) Lab data are processed through the Community Health Computer system located in the laboratory. Tests are ordered and results entered through this system.

- (b) Reports for the medical record, as well as status reports, are generated with the CHC system. Lab data tapes are produced monthly using the CHC system, and forwarded to the Data Processing Department to be sent to CDC with exam data tapes.

b. Data Coding

- (1) In order to provide consistent data, all of the examinations have been coded to the fullest extent possible. All of the medical exam results utilize a standardized coding scheme whereby the number "1" represents a normal condition, numbers "2-6" represent a positive finding, "7" indicates an incomplete result, "8" indicates "don't know" response from the participant or examiner and a "9" that the participant refused to answer or refused to have the exam.
- (2) Several other coding schemes are utilized where applicable. For the medical history and diagnostician's interview, ICD9-CM coding is utilized. For the chest X-ray, the American College of Radiology Index of Roentgen Diagnoses is utilized. Those codes applicable to the chest X-ray have been appended to the Veterans' Health Study Radiology Manual. The medical history also uses two additional coding schemes, the Collection and Processing of Drug Information: National Ambulatory Medical Care Survey for drugs and the Alphabetical Index of Industries and Occupations, 1980 Census of Population for occupations and hazardous chemicals. Copies of these code books are located in the Medical Records Office.
- (3) The electrocardiogram (ECG) utilizes a coding scheme specific to the Marquette Computerized ECG System. Each interpretation is assigned a 4-digit number, and it is these numbers that are input for the interpretation. A copy of the coding is included in the ECG section of the manual.

c. Blind Repeat Data

- (1) This section outlines the procedures for creating and identifying participants that will be selected for "blind repeats" of the medical exams and laboratory tests.
- (2) Through the course of the study, approximately 5% of all exams will be blind repeated, or the exam results blind interpreted, for quality assurance purposes. These repeated/reinterpreted exams will be compared with the original exam by the project Medical Director and by the Special Assistant for Quality Control and Scientific Affairs. The blind data will be sent to CDC, along with the original data for their review. A system has been developed that allows blind repeats to be done in a manner that will

keep the examiners/technicians blind to the original testing data, but will allow later correlation of the blind and original data.

- (3) The procedures for the blind repeats are separated into three distinct areas: 1) Medical History; 2) Medical Exams; 3) Laboratory. Generally they will follow the same flow. The participants that are to have a blind repeat will be identified by random number selection (see section on Pre-Arrival Procedures). Laboratory blind will be assigned a second ID number, which will be linked through Data Processing to the original number. Medical exam blinds are identified by the letter "B" which appears after the participant ID number. The blind exam/test is handled in the same manner as an original result, using the new ID number. The data will be flagged as a blind examination and posted to the participant's record. The hardcopy form generated at the time of the examination is filed in a separate section of the participant's medical record after completion of the Exit Interview. Blind data are reviewed for consistency with the original test data by the Medical Director and by the Special Assistant for Quality Control.

(a) Medical History

Special equipment has been provided to the Clinical Manager for monitoring administration of the medical histories. This equipment consists of an intercom system, which allows real time monitoring of Physician Assistant (PA) questions and the participants' responses. Records are made of any discrepancies between the answer given by the participant and that recorded by the PA/Clinic Manager.

(b) Medical Exams

The following exams are repeated on randomly selected participants: General Physical, Dermatology, Neurology, Pulmonary Function, Peripheral Vascular, Audiometry and Visual Acuity. Randomly selected Chest X-rays and Delayed Type Hypersensitivity tests are blind reinterpreted by appropriately trained personnel. All ECGs are overread by a cardiologist. Approximately 20% of NCV, QPS I, and QPS II data are reinterpreted by Dr. Joseph Arezzo, Rochester, NY. The routine administration of all of these tests by technicians is observed by the Clinic Manager and/or LMCI departmental supervisory personnel on randomly selected participants. All technicians are observed at least weekly.

(c) Laboratory

Laboratory tests on blood samples are divided among several different randomly selected participants, so that there are 3 participants that make up a single complete blind repeat. This is due to the amount of blood required for the battery of tests performed. Sufficient urine is available for urinalysis so that blind repeats of these tests are done on samples from randomly selected participant collections.

4. Total Business Systems (TBS)

Total Business Systems (TBS), an Albuquerque data processing services firm, is the subcontractor for data entry and data tape generation of data from Veterans' Health Study hardcopy data collection forms. TBS is responsible to the Data Manager for direction and performance. As the subcontractor, TBS is responsible for key entry of all hardcopy data, integration of data provided on IBM diskettes with key-entered data, and monthly provision of the combined data in the form of magnetic tapes.

a. Specific Areas of TBS's Responsibility

- (1) Establish a data entry operation at the Lovelace Medical Foundation Veterans' Health Study Examination Site. On site location provides greater data security and a reduced risk of document loss.
- (2) Provide backup services at TBS headquarters in case of emergency or backlog situations.
- (3) Key enter all data from hardcopy data collection forms with 100% verification.
- (4) Integrate data captured on IBM diskettes (Optical Scanning, CVLT and DIS data) with key-entered data by loading the diskettes to the TBS IBM mainframe located at TBS headquarters.
- (5) Develop and maintain screens and programs for generation of magnetic data tapes containing combined data from keytape entry and IBM diskette.
- (6) Provide combined data in the form of magnetic tapes at 6:50 BPI to Veterans' Health Study Data Management monthly.
- (7) Provide separate magnetic tape biweekly of the Birth Facts data to LVHS Data Management.
- (8) Develop and maintain documentation on the operation of the data management system, relating to data input, editing, data tape generation, and error correction.

- (9) Provide information to Veterans' Health Study Data Management personnel on all aspects of the system.

5. Participant Scheduling and Tracking System

The Participant Scheduling and Tracking System (PSTS) was written by Wolfe and Associates, Inc., an Albuquerque based contract programmer company. The software used for the system is Base III Plus. All call activity is entered via remote terminal in the scheduling department and updated to the master terminal daily. Daily, weekly and monthly reports are produced to monitor scheduling and personnel activity. The procedure manual and detailed program listings are kept in Data Processing for quick reference.

B. Data Flow

1. Pre-Appointment Procedures

a. Receipt of Potential Participant Lists

- (1) The participant list generated from Research Triangle Institute (RTI) contacts is received from CDC semi-monthly.
- (2) The participant file is sent on diskette along with a hard copy list to the CDC Onsite Monitor, who delivers it to the Data Manager.
- (3) Receipt of the potential participant list is noted on the Participant List Report, including the date and the number of participants.
- (4) The Data Manager notifies the Project Director, and/or the Deputy Project Director, and the Logistics Manager of the receipt of the list.

b. Potential Participant Lists

Several actions are taken when the list has been received and the appropriate parties notified.

- (1) The hardcopy list is given to the Logistics Manager by the Data Manager.
- (2) The Logistics Manager gives the list to the Scheduling Supervisor.
- (3) The Scheduling Supervisor/Schedulers use the list for reference purposes.
- (4) When not in use, the potential participant list is locked in the schedulers' filing cabinet.

- (5) The Data Manager runs two programs using the participant file.
- (6) Mailing labels are produced using the program LABEL.BAS to print the labels. Printed labels are given to the Scheduling Supervisor to be used for the initial mailing to potential participants.
- (7) The Scheduling Supervisor prepares the initial mailing to potential participants and sends it out.
- (8) The diskette containing the participant file is uploaded to the Participant Scheduling and Tracking System (PSTS). The new participants are assigned Lovelace ID numbers and hard copy worksheets are produced and given to the Scheduling Supervisor. These are used to manually record calls to the participants. Please see addendum on the PSTS.

c. Scheduling Activities

After the data have been uploaded and reports generated, scheduling activities begin.

- (1) After receiving the individual participant worksheets from Data Processing, Schedulers begin their contact efforts.
- (2) After a contact or an attempt has been made, Schedulers enter the results onto the appropriate form. All contacts, regardless of the outcome, are recorded.
- (3) When an appointment has been made, information regarding the date and participant is completed on a multi-part form: one copy is hand-carried to the travel agents; one copy is retained by the schedulers for their follow-up.
- (4) The scheduler then updates the master schedule board on the wall. This board reflects the number of participants scheduled for the next five months.
- (5) Any changes in participant address or phone number that are identified by the schedulers are entered onto the Locator Information Form. The form is taken to Data Processing where appropriate changes are made in the PSTS. The change form is then given to TBS to be keyed, put to tape and forwarded to CDC.
- (6) The travel agents utilize the information they receive from Scheduling to make travel arrangements for the participants.
- (7) The "TWA PAR" system is used for making travel arrangements.

- (8) Once arrangements are made, the agents hand-carry the form initiated by Scheduling back to the schedulers.
- (9) Schedulers enter the travel arrangements onto the appropriate form and file it with the original contact information on the participant.
- (10) A Travel Exception Report is generated by Data Management which contains a list of all participants that have been scheduled, but do not have travel arrangements. The report is received by the Lead Scheduler for use in follow-up of participants given to the travel agency.
- (11) Once the call information and/or travel information is recorded on the hardcopy worksheet, it is then entered into the PSTS by the Scheduling Clerk via a remote terminal located in the Scheduling Department.
- (12) The day's activity is retrieved from the XT and uploaded to the Master Scheduling Terminal each morning and again before 5:00 p.m. by Data Processing Personnel, who then upload the information to the Master PSTS terminal.
- (13) In addition to the Work Reports, several other reports are generated:
 - (a) Alpha Report (PST105) Produced weekly (Mondays) by Data Management and given to the Lead Scheduling Supervisor. This report lists all active participants. (Participants who are scheduled in the future and ones not scheduled as yet.)
 - (b) Archived Alpha Report (PST105)- Produced monthly and retained in Data Processing. This report lists all participants who have completed exams and all participants who have refused to participate in the study.
 - (c) Activity by Input (PST301)- Produced daily to monitor scheduling activity. Copies are distributed to the Project Director, Deputy Project Director, Logistics Manager and Scheduling Supervisor.

2. Pre-Arrival Procedures

a. Participant Advocate Activities

Each Monday morning, participant worksheets are printed and given to the Advocates in addition to various Block Date Reports. They contain the participants scheduled for two weeks hence. Participants are assigned to Participant Advocates based on the first day of the participant's examination stay. One Advocate is assigned to each arriving block.

- (1) The Advocates contact each of their assigned participants to explain details of the study and answer questions. They record any pertinent information obtained during this interview, such as the attitude of the participant, if the participant is staying extra days and if anyone will be accompanying him.
- (2) Advocates notify the clinic and the laboratory of any changes in the list for each block date.
- (3) The week prior to arrival of the participants, the Advocates generate arm bracelets and name tags for each participant.
- (4) Any changes in the original scheduling of participants occurring within two weeks prior to the participants' arrival are noted by the Advocates, who notify all study areas. This is done through completion of a "participant status change form" which is distributed to the Scheduling Supervisor, Clinic Manager and Nurse, Medical Records Specialist, Data Manager and the Lab Q.C. Supervisor. If scheduling is notified of an addition or cancellation from the participant, a multipart form is distributed to Triple A and Participant Advocates.

b. Laboratory Report

Each Monday, Data Management generates a report of the following week's scheduled participants plus applicable blind (repeat test) numbers. This report is sent to the Laboratory where demographic information is entered into the computer.

- (1) The appropriate lab tests are requested and participant-specific labels for the blood sample tubes and urine containers are generated.
- (2) Laboratory technicians make up sample packets for each participant day.

c. Daily Schedule Report

A list of participant names, ID numbers, total participant numbers and advocate assignments is generated by Data Management for each block day, and is sent to all study areas on Arrival Day (Day 1). The clinic nurses use this report to schedule examination rooms, and Medical Records uses the list to set up participant charts.

d. Designation of Quality Assurance Blind Repeat Sequence Numbers

- (1) Participants designated to have additional blood drawn for blind repetitions of clinical laboratory tests are identified on the Monday laboratory report. Random number selection based on the number of participants scheduled for

that week is done by the Special Assistant for Quality Control and Scientific Affairs. A minimum of five percent of each of the total clinical laboratory tests is repeated. Sampling is achieved as described in the "Data Collection Procedures" section.

- (2) One blind repeat or blind reinterpretation or observation is performed for each medical exam each day. For weeks during which less than 23 participants are scheduled per block, this represents an oversampling; in other words, greater than 5% of the tests are being blinded. However, in order to make allowance for potential scheduling problems such as no-show participants, participant refusal to repeat an exam, or unpredictable time constraints, blinds are scheduled every day so that, on balance a 5% repeat level will be achieved.
 - (3) Blind repeats and blind observations are assigned times and participant schedule numbers by the clinic nurse according to the availability of rooms, physicians or other qualified observers, and free time in the participant's schedule. These times will remain fixed, while the participants assigned to a particular schedule are slotted into that schedule in a random manner.
 - (4) The clinic nurse is responsible for making sure that the designation "Blind" is recorded on the data collection form after the test or examination has been completed and the form has been returned to her desk, and that the participant ID number is followed with a "B."
 - (5) Oversight of blind repeat scheduling and performance is the responsibility of the Special Assistant for Quality Control and Scientific Affairs.
 - (6) For laboratory blinds, the selected sequence numbers are reported to the Data Manager or Lead Data Processor who proceed with assignment of identification numbers.
 - (7) The blind cross-reference program is accessed through BSTS.
 - (8) The selected participant ID number is entered and a new (blind) participant number is generated.
 - (9) Copies of the above report are distributed to the Laboratory Quality Assurance personnel, and Medical Records personnel, so that sample labels and data records may be generated.
- e. Participant Schedules

An individual schedule is generated for each participant, according to their sequence number.

(1) The clinic nurses make up an individualized list for each participant designating the order and time for each medical exam, and the room in which the exam will take place. The schedule also assigns breakfast, lunch and break times. The order of events remains the same for each participant sequence number in every block.

(2) Participants are assigned to morning or afternoon group psychological testing and morning or afternoon individual psychological testing by the head neuropsychologist. Each participant is assigned to a single technician who administers all of the individual tests to the participant.

3. Post-Arrival Procedures

a. Arrival Day - Day 1

Advocates meet and orient participants. At this point, they become aware of any no-show participants and notify all study areas.

b. Medical Day - Day 2

Upon arrival at Lovelace Medical Center, participants are greeted by the Clinic Manager who provides each with their individual schedules for the day. After receipt of the schedule and a brief tour, the participants proceed through the day according to their schedules.

(1) Medical Exams/Tests

- (a) At each exam/test station, the participant is checked off the individual room schedule by the examiner.
- (b) The exam or test is performed, and upon completion results are entered onto a data collection form.
- (c) The form is signed by the examiner and taken to the clinic nurse. The clinic nurse checks off the exam on the master schedule and places it in a file in her desk. The clinic nurse is responsible for assuring that all exams/tests have been completed prior to the participant's departure that day, and that results have been generated.
- (d) The exam forms are delivered to the Medical Records Analyst periodically throughout the day. The medical records analyst performs an extensive quality control check, looking for blank required fields, inappropriate skip patterns and correct LMF ID numbers.

- (e) The ECG and Pulmonary Function Test (PFT) must be interpreted by a cardiologist and pulmonary disease specialist, respectively. The ECG is transmitted through the phone lines to the Cardiology Marquette System. An unconfirmed reading is generated which is read by a cardiologist, and then a confirmed reading is generated. The PFT is hand-carried by Medical Records personnel to the Pulmonary Department where it is read by a pulmonary physician. Once read, both the ECG and PFT are picked up by Medical Records and filed in the participant's chart.
- (f) The Medical History is sent to the Medical Records Technician for coding of medical conditions, hazardous chemicals, drugs and occupations. Once coded, the history is filed in the participant's chart.
- (g) All other exams/tests are sent to Medical Records for filing in the participant's chart. The Medical Records clerk checks off each exam result as it is received in Medical Records. The Medical Records clerk checks the form to see that the correct name and participant ID number have been recorded, and that the data are complete. This person is the second check in assuring that all exam results are received. Once checked off, the results are filed in the record. If an exam is found to be missing or incomplete, the Medical Records clerk follows up with the clinic nurse to ascertain its whereabouts or complete it.
- (h) Prior to the results interview, the medical record is reproduced. The copy is given to the participant prior to his departure. Copies of any blind exams, along with the original data, are made and filed appropriately for abstracting and analysis by the Medical Records Analyst and the Special Assistant for Quality Control and Scientific Affairs.
- (i) The original exam/test forms are batched with forms of the same type, and a Batch Control Slip is filled out, listing the forms along with the block data. A copy of the Batch Control Slip, along with the exams, is forwarded to the Data Processing Department.
- (j) In the Data Processing Department, the exams are counted a second time. A batch number is given to the appropriate exams. This number is recorded on a Batch Control Register which lists all exam batches for the blockdate.

(k) Batch numbers are assigned using the exam ID code as the first two indicators, followed by the exam date.
[Examples: AE0312 - Audiology Exam; GP0312 - General Physical; QI0312 - QPS I Exam, etc.]

(l) Batched exams are taken to TBS for data entry and data tape generation. Upon completion, the exams and a computer listing of keyed exams are returned to Data Processing.

(m) The date on which a particular batch of exams goes to TBS for data entry, and the date on which it is returned to Data Processing are noted on both the Batch Slip and the Batch Control Register.

(n) When TBS is unable to key an exam due to range check errors, illegibility, or missing data, the exam is pulled from the batch and taken to the Data Processing Department.

(o) Errors are researched and, if possible, corrected by Data Processing. If the problem is missing data or range check discrepancies, the exams are forwarded to the Clinic Manager.

(p) Once the exams are completed or corrected, they are sent back to Data Processing.

(q) After receiving the corrected exam, Data Processing returns it to TBS who places it back in the appropriate batch.

(r) Copies of all Batch Control Slips are kept in Data Processing, as well as being sent to TBS. Thus the status of any exam is traceable at all times.

(2) Laboratory Data

The results from the laboratory are collected in a slightly different fashion than the other data. The lab has a Community Health Computing system that manages data within the lab. This system is utilized for data collection and for generating hard-copy reports for the medical record.

(a) The test battery is ordered by entry into the CHC system prior to the participant's arrival. The ordering is done upon receipt of the Laboratory report that is received the Monday prior to the next week's arrivals. This triggers both an expected schedule and collection labels.

(b) On the morning of Medical Day (Day 2), the 12-hour urine collections and blood samples are obtained and

input into the system by the phlebotomists or specimen processing personnel. The fact that specimens have been collected is entered on the computer terminal.

- (c) As tests are completed, the results are entered by laboratory technicians. Results are entered into the laboratory computer in an unverified state, to be verified later.
- (d) The system produces the needed exception reporting for incomplete tests, and produces the final result reports.
- (e) On the morning of Day 3 (psychological test day), the initial result reports are produced. These reports include all of the tests ordered and show the status of each; either a result or an incomplete message. The Medical Records clerk picks up these reports and files them in the participant records.
- (f) On the afternoon of Day 3, a second result report is generated. This report includes only those tests that were incomplete on the previous reports. The Medical Records clerk picks up these reports and files them in the participant records.
- (g) On a daily basis, a tape containing the laboratory participant data is created by the laboratory computer.
- (h) Laboratory Quality Control Data Management - A quality control program, written by CDC, is used to produce quality control charts and analyses for laboratory tests.
- (i) Data for these assessments are obtained using clinical laboratory standard materials that are run along with sample materials, and are used to calibrate and standardize the instruments. Control results are entered into the CHC system using special ID numbers that identify the results as controls.
- (j) Laboratory Quality Control Supervisors have an IBM XT connected to the CHC system with a terminal emulator package. This software allows capture of files from the CHC system. Several times daily, quality control data are downloaded from the CHC system into the IBM PC/XT, and then run through the quality control program. Reports, charts, and graphs are produced on a dot-matrix printer.
- (k) Once a week, the QC supervisors create a data file of that week's control data. The supervisors contact the CDC Statistician who makes his/her IBM XT ready to receive the data. The data are then transmitted to

Atlanta through the communications package Crosstalk. A file named "CALLCDC" sets the necessary protocol parameters for the transfer.

c. Psychology Day - Day 3

On Day 3, participants undergo the psychological battery. As each test is administered the technician records the test responses and/or results onto OCR forms or other worksheets.

(1) Key entry forms

- (a) Completed data forms for the Wide Range Achievement Test, Word List Generation, Handedness, Grooved Pegboard, Group Validity Debriefing, and Individual Validity Debriefing are sent to Data Processing and then on to Medical Records to be filed in the participant's chart.
- (b) Before filing, Medical Records clerks check the forms for completion and for correct name and participant ID number.
- (c) After the Exit Interview has taken place, batching and key entry procedures are followed as described for the Medical Exams.

(2) Optical Scanning forms (except MMPI)

- (a) Completed data forms for the Army Classification Battery, Combat Exposure Index, Wechsler Adult Intelligence Scale, Delayed Rey-Osterrieth, Paced Auditory Serial Addition Test, and the Wisconsin Card Sort are sent to Data Processing by Neuropsychology as the tests are completed.
- (b) Data Processing records the exams received for each participant in the Exam Log Book. The Lead Technician or Chief Neuropsychologist is contacted if any exam forms are missing at the end of the day.
- (c) All scanning forms are checked prior to scanning for stray marks and incomplete erasures. In addition, all necessary information (participant number, date, test number, tester code, and scorer code) is checked for completeness and accuracy.
- (d) Operation of the Optical Scanner:
 - (i) Turn on printer.
 - (ii) Turn on scanner (.C should appear on panel momentarily).

- (iii) Turn on IBM XT computer.
- (iv) Enter date and time.
- (v) When C> prompt appears, type in NCS2; press the "enter" key.
- (vi) A screen will appear on the monitor; at the prompt it will say "Enter Function"; enter Function "1" Process Standard Test Group.
- (vii) Place sheets in scanner bin with the timing marks at the left and the Skunk marks on the same edge.
- (viii) Push the stack toward the scanner until the green light on the hopper comes on. If the light changes to red, the stack has been pushed in too far. Pull the stack back until the light changes to green.
- (ix) Press "Start" on scanner panel to begin scoring. After all forms of first exam type have been scanned, place next exam group in scanner bin and proceed by pressing "Start" on scanner panel.
- (x) When all forms have been scanned, enter "ESC" to get back to the menu; enter 3 (Exit back to DOS) and the C prompt will return.
- (xi) Place formatted diskette in Drive A and type:
 - Copy AQ.DAT A:
 - Copy CE.DAT A:
 - Copy PA.DAT A:
 - Copy RE.DAT A:
 - Copy WA.DAT A:
 - Copy WC.DAT A:

(3) Optical Scanning - Minnesota Multiphasic Personality Inventory (MMPI)

- (a) MMPI forms are sent to Data Processing by Neuropsychology technicians, where they are logged as described for the other scanning forms above.
- (b) Data Processing personnel check the forms for stray marks and incomplete erasures, and check to see that all necessary information is completed and correct (participant number, date, test number, tester code, scorer code).

(c) Operation of the Optical Scanner:

- (i) Turn on printer.
- (ii) Turn on scanner (.C should appear on scanner panel).
- (iii) Turn on IBM XT computer.
- (iv) Enter date and time.
- (v) At the C> prompt type in MMPI; press the "Enter" key.
- (vi) Screen will appear on the monitor giving various options. Press the space bar down until the required option is highlighted. (In this case the necessary option is "Score and Report"). Press the "Enter" key; the highlight will automatically go to "Scanner"; press "Enter."
- (vii) Place forms in scanner bin so that the skunk marks are going into the scanner, and the timing marks are on the left.
- (viii) Push the stack toward the scanner until the green light appears. If the light changes to red, the stack has been pushed in too far. Pull the stack back until the light changes to green.
- (ix) Press "Start" on the scanner panel to begin scanning. Only five forms will be scored at a time.
- (x) The program will automatically go to a demographics screen. Enter any missing information and press "Enter."
- (xi) The program will then bring up the first record that has any missing data information. Enter correct information from the test form. If the information is not present on the form (not answered) enter a zero.
- (xii) When all of the information is complete, the program will score all 5 exams and then will ask if the information should be saved; press the space bar until the "yes" is highlighted; press the "Enter" key. Place a diskette in drive A; press the "Enter" key.

(xiii) After all five reports are printed, another menu will appear on the screen, press the space bar until "Cancel" is highlighted; press the "Enter" key.

(xiv) The first menu will reappear; repeat steps A through E described above until all MMPIs have been scanned.

(xv) After all forms have been scanned and printed, press the space bar until "Quit" is highlighted; press the "Enter" key.

(xvi) At the C> prompt type in:
Del *.SCR; enter
Del CATALOG; enter
Copy A:*.SCR; enter
Copy A:CATALOG; enter

Type in NCS2 and enter. This will bring up the scanning menu; choose Option #2 ("Convert MMPIs"); enter.

(xvii) When the conversion is finished, choose Option #3 ("Exit Back to DOS"); the C prompt will reappear.

(xviii) Type "Copy MM.DAT A:".

(4) The CVLT exam is keyed by Data Processing the morning following receipt from Psychology. Because it is not needed for debriefing, it is not sent to Medical Records until after keying.

A copyrighted CVLT scoring diskette must be used.

(5) The DIS test is processed by a slightly different method.

(a) The DIS is manually edited by technicians after the test is administered. Once this edit is complete, exams are forwarded to Data Processing in batches of 10 exams each.

(b) Data Processing reviews the batches, names them and forwards to TBS.

(c) Once keyed and verified, TBS downloads the batches to a diskette via an IBM AT and returns diskette and hardcopy exam to Data Processing. These are then sent back to the DIS Editors who pass it through a "cleaning" program which further edits the data. If errors are found during this edit, the test and the error printout are returned to the Psychology technicians.

- (d) The technicians review and correct the errors, and then return the test and corrections to the DIS editors.
- (e) DIS editors enter the corrections to the original data file. The data file is then passed through the cleaning program, which edits the data again. This process repeats itself until no errors are detected.
- (f) A diskette containing the final data file is returned to Data Processing. The diskette is then sent to TBS where a data tape is created. This tape is sent back to Lovelace Data Processing who forward it to CDC where the data are run through an SAS program and diagnoses are generated.

d. Diagnostician Reader Medical Data Review - Day 3

On the evening of Day 3, Medical Records staff pull the participant medical records and forward them to the Diagnostician Reader. The Diagnostician Reader reviews the charts and records his/her findings on the Diagnostician Reader Form. This form is filed in the medical record and is reviewed by the Diagnostician Interviewer after he/she has arrived at conclusions based on an independent review of the medical record.

e. Exit Interview - Day 4

On Day 4, the participants are interviewed by a Medical Diagnostician Interviewer and a Psychologist.

- (1) Medical Records personnel prepare the medical charts and give them to the advocates for transport to the interviewing site at the hotel.
- (2) The Diagnostician Interviewer reviews the record and records his/her findings on the Diagnostician Interviewer Form. He/she then reviews the Diagnostician Reader's findings and arrives at a conclusion.
- (3) The Diagnostician Interviewer then interviews the participant. The participant is asked to sign a form indicating that he was given the results of his medical exam.
- (4) The Psychologist interviews the participant informing him of the psychological test findings. Another form is signed by the participant stating that the test results were explained to him.
- (5) Prior to leaving the interview session, the participant's Hypersensitivity Test (CMI) will be read by the participant advocate and the results recorded on the hypersensitivity form in the medical record.

(6) Copies of abnormal chest x-rays and a summary of medical and psychological test results are given to the participant to take home with him. All other medical information is forwarded to the participant or his personal physician according to the participant's expressed wishes. If the participant so designates, a summary of psychological tests and results is sent to a psychologist, psychiatrist or other mental health provider, as designated on the signed medical records release form.

(7) After the interviews are complete, the medical records are returned to Medical Records.

f. Blind Repeat Data Management

- (1) The participants are selected randomly and new ID numbers generated as earlier described.
- (2) Exams and/or lab tests are performed, monitored, or reinterpreted.
- (3) Results are keyed and verified by TBS (except lab) using the newly assigned ID number.
- (4) Results are forwarded to the Medical Records Department
- (5) Medical Records staff reference the blind repeat cross-reference list to identify the correct participant record. The results are filed in a separate section of the participant's record after the exit interview has taken place.

g. Data Tape Preparation

Exam Data tapes are produced and sent to CDC each month. Data collected on diskettes (scanning, CVLT and DIS) are sent to TBS to be uploaded via an IBM AT to their mainframe and merged with the key entry data. The CVLT and DIS data are on a separate tape from all other data. Both tapes are sent to the Data Manager along with various reports, i.e., Participants Billed This Run, Incomplete Participants and Record Keys of all exams on the data tapes. These tapes along with the aforementioned lab data tape are sent to CDC. Copies of the record keys and Participants Billed This Run are also included with the tapes.

h. Error Correction Process

After CDC has received a data tape and has uploaded the data to their mainframe computer, any range check errors found are sent to LVHS Data Processing on the hardcopy form for correction. Corrections are recorded on the hardcopy and returned to CDC.

Once CDC has loaded the range check corrections, a skip pattern logic edit is produced on hardcopy, sent to LVHS and corrected in same manner.

i. Edit Specifications

Edit Specifications for each of the individual exams are retained in the Data Processing Department.