Q.204 "A lot" should be emphasized. The respondent defines "a lot."

Q.204A The respondent is asked for the age when he first lied "a lot," not when he first told a lie.

Q.206 "Intentionally" should be emphasized. This question assesses vandalism, that is, intentional damage to someone else's property.

Q.207-ED
PROBLEM: R's answer to arrested or sent to juvenile court was "yes, traffic court." How to code?
DECISION: Clarify that R. was in fact arrested or sent to juvenile court, as many juveniles are sent through adult traffic courts for minor or first-time offenses in some states.

Q.208 This question begins the section on behaviors as an adult. Thus, the interviewer must emphasize "since 18." The interviewer should note that positive adult symptoms are coded 5*. The asterisk makes it easy to identify the adult items when looking back to review symptoms for INTERVIEWER BOX LL and Qs. 232 and 234.

Q.208-ED
PROBLEM: If in Q.163 R. was arrested since 18 for disturbing the peace, etc., while drinking, should Q.208 be coded as positive as well?
DECISION: Yes, because this meets criteria for both alcohol and antisocial diagnosis.

Q.208-ED
PROBLEM: R's answer to being arrested for anything other than traffic violations was "no," but in Q.208B he volunteered he had in fact been convicted of a felony, but that it was for (3) DWI's. How to code?
DECISION: When habitual traffic violations such as (3) DWI's become severe enough to be a felony, they are no longer traffic violations, but criminal behavior, which is the intent of this Q. Code (5)'s throughout.

Q.208.B-ED
PROBLEM: R. was convicted of a felony before age 18. Does it get coded here?
DECISION: No. Q.208-Q.231 are only concerned with problems occurring since age 18.

Q.209 Only moving traffic violations count, and there must have been at least four. These may have occurred at any time in the respondent's life. DO NOT INCLUDE PARKING TICKETS.

Q.209-ED
PROBLEM: Do the four traffic tickets apply to the categories of running a light, speeding or causing an accident only or for other moving violations as well?
DECISION: Question applies to all moving violations except DWI or DUI which are picked up elsewhere.

Q.210 This is the first question about sexual attitudes and behavior. "Sexual experience" and "sex life" are synonyms and mean sexual intercourse. There are a few people who, when the interviewer first says to them that they are going to discuss sexual experience, will say, "I don't want to talk about that." The interviewer should suggest trying a few questions and not answering any that they don't care to, just to see what the questions are like. If they refuse this suggestion, the interviewer follows the instructions in the SUPPLEMENT USED BOX (skip to Q.S23).

A person who has never had sexual intercourse may volunteer that information here. If so, the interviewer follows the instructions in the SUPPLEMENTAL USED BOX (skip to Q.S23). This skip instruction exempts respondents who have never had sexual relations from questions about sexual experience, marital problems, transsexualism, and homosexuality. The DIS does not follow DSM-III in this regard for studies in the general population because of concern that people without sexual experience are likely to be embarrassed by questions on these topics.

Q.211-S2 The PFC is used for these questions on sexual experience.

Q.211 EMPHASIZE "physically painful."

Q.212 "Period of several months" should be emphasized. The phrase in parentheses is to be used if in the preceding question the person reported physical pain during intercourse. If lack of pleasure was attributable only to pain, the answer to Q.212 is "No."

Q.213 The word "other" in the parentheses is read if Q.212 is positive. The phrase in the second parentheses is read for all men, regardless of what they answered previously.

Q.S11 This begins the section on homosexuality. In order to be coded 5, the respondent had to have voluntarily had homosexual relations since his 18th birthday. If the respondent volunteers that his only homosexual experiences were in jail or forced, the interviewer codes (2) and skips out of this section. The interviewer also skips out if there have been no sexual relations with a member of the same sex.

Qs.S14-S18 Homosexual attraction as well as performance is required for a diagnosis. Those never sexually attracted to members of their own sex are skipped out of this section.

Q.S18 Read "or did it go away on its own" if S17 is 5.

Q.S19 With this question, the interviewer returns to antisocial personality questions. It should be noted that the INTERVIEWER INSTRUCTION BOX above Q.S19 restricts this question to currently

or formerly married respondents. If the respondent has been married more than once, the word "any" should be included. A "Yes" requires homosexual or heterosexual relations with three different persons other than the spouse while still married. This question is looking for casual infidelity, not a serious extra-marital love affair.

Q.S20 This question assesses promiscuity. Both homosexual and heterosexual sexual relations count. When reading this question, do not read the phrases in parentheses--(including your wife/husband)--since it may make the respondent limit himself to times he was married. If the respondent asks the interviewer whether to include his spouse when totaling up the number, the answer is "yes" (i.e., the spouse plus nine others in one year qualifies).

Q.S21 It should be noted that being paid for either homosexual or heterosexual sex counts.

Q.S21-ED
PROBLEM: Does being paid for sex always have to be in cash, or does being taken care of (i.e., a gigolo) and other services bartered count as well?
DECISION: Does not have to be cash only. Can be whatever R. considers as being paid for having sex.

Q.S22 It should be noted the respondent had to have made money from this activity.

Q.S23 This question asks about illegal activities. Buying stolen property means acting as a "fence" (i.e., buying with intent to resell) or buying for personal use despite knowing the object had been stolen. Selling stolen property includes selling property from one's own thefts or acting as an agent for a thief. A positive response does not require being found out or arrested.

Q.S-22,
S-23-ED
PROBLEM: Does "buying or selling" have to entail turning a profit?
DECISION: No.

JJ INTERVIEWER INSTRUCTION BOX JJ indicated that if the respondent has neither married nor lived with someone as married, the interviewer codes 5 and skips to Q.217. This is another coding exception, where a "No" is coded 5.

Q.214 The question refers to the respondent's leaving home without the spouse's agreement to the departure. Asking the partner to leave does not count. If multiple partners, walking out on any one "for at least several weeks" counts.

Q.215-ED
PROBLEM: R. said he did not beat wife, but he shot at her. How to code?
DECISION: Code 1 here. Q.218 will pick up weapon, etc.

Q.215-ED
PROBLEM: Does the wife/partner have to be a female. QS. intent was spouse abuse?
DECISION: If Q.11.1 is a yes, and a homosexual partner, then Q.215 will include a male partner as well.

Q.216-ED
PROBLEM: Does the antisocial section include before age 18?
DECISION: No. This section includes adults only or more than 18 years of age.

Q.216-ED
PROBLEM: If R. answers yes to hitting someone hard enough so that he/she had bruises, etc., but it was only in the line of duty, how to code?
DECISION: Code 1. This applies to Q.217 as well.
Revision: Code 1 also for organized sports activities such as football, boxing, judo, etc.

Q.217-218 Fights are scored as positive even if the respondent did not start the fight.

Q.217 Fights with spouse or lover do not count; they are covered in Q.215. Exclusively verbal fights do not count.

The SPECIAL INSTRUCTION BOX directs the interviewer to exclude fights in the line of duty by persons whose occupation requires it, such as policemen, boxers, bouncers, or soldiers.

Q.218 The weapons listed are examples. Any object used as a weapon counts.

The SPECIAL INSTRUCTION directs the interviewer to exclude use of weapons required by the respondent's job. "Using a weapon" is trying to hurt someone with it, whether or not one succeeds. In the case of a gun, aiming counts even if the trigger is not pulled.

Q.219 The SPECIAL INSTRUCTION indicates that the interviewer is allowed to ignore job changes that the respondent volunteers were due to changes from one life stage to another, like graduation, marriage, maternity. If a person has both a full-time and part-time job, changes in his part-time job do not count.

Q.219-ED
PROBLEM: How to code self-employed construction contractor who has many construction assignments or jobs in 5 years?
DECISION: If R. works for himself, code as one continuous job. If R. works for another, code as separate jobs.

Q.219-ED
PROBLEM: Does Army count as a job?
DECISION: No.

Q.220 The respondent has to be fired from more than one job to be coded "Yes." Quitting in anticipation of being fired counts as being fired.

Q.221 "Three times or more" should be emphasized.

The SPECIAL INSTRUCTION, as for Q.219, excludes quitting to return to school or because of a major life stage change.

Q.222 This question uses the PFC. When probing use the phrase "late or absent three days a month or more."

Q.222-ED
PROBLEM: Due to a physical illness, R. was absent for 2 months straight. Do we take an average here to meet the criteria for absent an average of 3 days a month or more? There is no code (4).
DECISION: No, do not average. Take question literally for each month. Intent is to find irresponsibility due to excessive tardiness or absenteeism on an ongoing basis rather than a block of time and regardless of reasons for it.

Q.223 This question identifies persons who had at least six months of unemployment in the last five years, in addition to any time explained by physical illness, being a student, or house-husband or being retired.

If the total time out of work is less than six months, the interviewer enters the time and skips to the next question. Periods of wanting a job but not finding one, psychiatric disability, and not wanting to work, all count as unemployment. As soon as the interviewer accounts for a total of six months for one or more of these reasons, he codes 5 and skips out.

For persons who have been out of the job market for all of the last five years, the interviewer should enter 60 months. If the respondent has seasonal work (e.g., construction), the normal lay-off is not counted as unemployment.

Q.223-ED
PROBLEM: R. traveled around for 6 months while laidoff. Does this count as being without work?
DECISION: No. Planned lay-offs with date of return to work are similar to seasonal employment. Both count as having a job.

Q.223-ED
PROBLEM: How do we treat the totally disabled who are not employed?
DECISION: Take the number of months without work and follow through question the same as with other unemployed respondents.

Q.223-ED
PROBLEM: How to code if less than a month out of work?
DECISION: Code (00) as it is not a significant amount of time and remains consistent.

Q.223-ED
PROBLEM: R. was a professional gambler for last five years. It was his only means of support. Does this count as being employed?
DECISION: Yes. Code 00.

Q.223.B-ED
PROBLEM: R. was not able to look for work due to hospitalization. Does this count here?
DECISION: R. must be able to actively look for work. So if in hospital, etc., don't count here.

Q.223D The interview should read "besides that" if there are entries in either Qs. 223B or 223C.

Q.223E This is a query to the interviewer. (NOTE it is in caps and therefore not to be read to the respondent.) If the interviewer has skipped to E from B or C, the answer is "Yes." If D has been asked, B and C must be added to D to answer E.

Q.224 The alias may be used only briefly. Giving a false name to a nosey person is coded 5. The interviewer should not try to judge whether the alias was used for a "good" reason.

Q.224-ED
PROBLEM: R. said at age 15 that he changed his name from mother's name to father's name which he presently uses. It was not changed legally. Does this meet intent of using alias or assumed name?
DECISION: Since he used one of the family names, it does not meet intent. Code 1.

Q.224-ED
PROBLEM: R. said he worked as a collector at a bank and bank policy required using another name to protect his identity. How is this coded?
DECISION: If alias is used only for occupational purposes, code 1.

Q.225 The respondent defines "pretty often."

Q.226 This question asks about wanderlust or vagrancy. The interviewer should not include people whose only travel without prior arrangements was during vacations or while on leave from their job or school. We are looking for people who do not have a job or school to return to.

Q.227 This question is used to assess transiency. "For at least a month" should be emphasized. During this time the person must have no home address.

Q.231 "You had spent the food money" should be emphasized.

LL The 5*s are codes for adult antisocial symptoms. This instruction keeps the interviewer from having to ask questions about onset, recency, and course for persons who clearly will not meet the criteria for antisocial personality.

Q.233A If the respondent did not have any 5* behaviors between ages 18 and 25 (Q.233=1), this question asks if the absence was due to a lack of opportunity.

EXAMPLES: The respondent did not beat his wife or child between ages 18 and 25 because he first married at 26 and his first child was born when he was 27. Or the respondent was never arrested between ages 18 and 25 because he was in jail the whole time.

A code of 5 means the respondent lacked the opportunity to carry out these behaviors. A code of 1 means the respondent had the opportunity but did not do them.

Q.234 The interviewer should note that, like drugs and alcohol, antisocial personality has a "within the last three years" category for recency. This is because antisocial behaviors may occur only sporadically. At least three years must elapse before it is reasonably certain that the antisocial behavior has ended.

M. Pathological Gambling, Questions 235-239

Description

The essential features of Pathological Gambling are a chronic and progressive failure to resist impulses to gamble and gambling behavior that compromises, disrupts, or damages personal, family, or vocational pursuits. Characteristic problems include loss of job due to absence in order to gamble, defaulting on debts and other financial responsibilities, disrupted family relationships, borrowing money from illegal sources, forgery, fraud, embezzlement, and income tax evasion.

Special Instructions

The Probe Flow Chart is not used in this section.

Question-by-Question Specifications and Edit Decisions

Q.235 If the respondent never bet or bet only once, the interviewer skips out of this section to Q.239.

Q.235D Borrowing to gamble must have created a problem for respondent. The interviewer should not count simply borrowing small sums from friends when his own cash was exhausted at a racetrack or in a card game. This question is not included in Box NN.

Q.235-ED PROBLEM: Is bookmaking gambling?

DECISION: Yes.

Q.237 It should be noted that gambling has a "within last 3 years" recency probe. Like giving up other antisocial behavior, giving up gambling is not taken seriously until it has lasted at least three years.

N. Post-Traumatic Stress Disorder, Questions PT35-PT47

Description

This diagnosis is given when symptoms are suffered following exceptional and traumatic events that have been personally experienced or viewed. The diagnosis requires reexperiencing the event in dreams or through recollections, numbing of responsiveness, and showing two of six other symptoms, including hyperalertness, guilt about survival, sleep disturbance, cognitive problems, avoidance of recollection, and intensification of symptoms when exposed to similar events. These traumatic events may be single events (e.g., mugging) or a group of events (e.g., military combat) and may be manmade (e.g., fire or car accident) or natural (e.g., flood, earthquakes), but they must be sudden and OUTSIDE THE RANGE OF USUAL HUMAN EXPERIENCE, i.e., "EXCEPTIONAL." The respondent may have had some of these symptoms after other experiences such as business loss, divorce, or witnessing a natural death, but the diagnosis would not be made because these events do not qualify as exceptional.

Special Instructions

The diagnosis is made for each of 8 types of events: combat, experiencing or viewing an accident, physical attack, witnessing a death or accident, threat, receiving or witnessing a close call, natural disaster, receiving news of an unexpected death or injury. Some respondents may have more than one experience within an event category.

The interview provides lines on which to record experiences that produce symptoms but do not qualify as "exceptional." However, these reactions to adversity are not probed or used in the diagnosis. The experiences that are not to be counted as traumatic experiences include reading a scary novel, watching a TV program or movie that was scary, having an illness or nervous breakdown, receiving bad news other than a loved one's death or serious injury, and witnessing a natural death. These lack the essential feature of this disorder according to DSM-III criteria, a stressor generally outside the range of usual human experience. These experiences are recorded but are not probed in subsequent questions.

After a traumatic experience is reported to have caused a symptom, the question covering each remaining symptom is introduced by asking whether the traumatic experience caused that symptom as well. Then respondents are asked if any other traumatic event caused that symptom.

Question-by-Question Specifications and Edit Decisions

PT35 Important words in this question are "happen to you." If the answer is "Yes," the "A" question elicits information about the event.

PT35A Examples are to be recorded on the dotted line next to the appropriate event and the '5' in Column A is then circled. If the event does not qualify as "exceptional," it is recorded below Item 19.

PT35B-ED
PROBLEM: Can R. be in a predream or dream state to act or feel as though some horrible experience was happening again and code a "yes?"
DECISION: No. If R. was not completely awake, this does not count. Always probe to make sure. Otherwise, it is part of PT35.

PT35B-ED
PROBLEM: If R. says yes to a problem, but refuses to say what his experience was, how to code?
DECISION: Show or read card D. If A-K categories, code (5) and enter "refused to name." Continue asking Qs for experience. If R. still refuses and it is not an L-Q experience, code (5) in "other trauma." If R. still refuses to narrow it down, code 9 for all categories and ask no further about experience. Do not resume 9 codes either.

PT35B This question is asked of all respondents, whether or not an event was mentioned in A. The experience is to be recorded on the appropriate line and the '5' in Column B circled.

PT36 The instructions that introduce this question direct the interviewer to look back to see what traumatic events have produced symptoms so far, to circle the corresponding numbers in the list of events below this question, and then to ask whether these events also caused the symptom covered in this current question. Only after events already known to have caused symptoms are asked about, does the interviewer go to A to ask whether events not yet mentioned have caused this symptom. A similar set of instructions will precede each of the remaining post-traumatic stress symptom questions (PT37-41).

PT36A If Q.PT36 was asked and coded 5 (yes), this question is read with the parenthetical word "other." If PT36 was not asked because no traumatic event had yet been identified, the parenthesis is omitted.

PT36B — As in PT36A, the "other" in parentheses is used only if the main question received a positive answer.

These instructions for asking PT36, PT36A, and PT36B are to be followed for the remaining symptom questions, PT37-PT41.

PT38 — If the respondent mentions a particular sleep disturbance such as "falling asleep," the interviewer should circle that phrase and use it in subsequent probing.

C.1A — This INTERVIEWER INSTRUCTION BOX must be scored in order for the interviewer to know which question is next asked. If there is no positive symptom in PT35 through PT40, the interviewer skips the rest of the PTSD section. If there has been a positive symptom in PT35-40, PT42 is asked.

PT42 — This question is repeated for each traumatic event that caused a symptom. The bolded words in Q.PT35-40 are used to list the symptoms caused by that particular traumatic event. For example: Respondent was in a flood that caused nightmares (Q.PT35) and was assaulted, which caused both nightmares (Q.PT35) and hyperalertness (Q.PT37).

I: CIRCLES NOS. 5 AND 13. When you were in a situation that reminded you of the assault, did you find that any of the problems you had got worse, problems like nightmares or being jumpy or easily startled?

R: Not the nightmares, but every time I passed the corner where I was mugged, I would be extra jumpy for the next few hours.

I: CODE 5 NEXT TO ITEM 5. When you were in a situation that reminded you of the flood, did you find that your nightmares got worse?

R: No.

I: CODE 1 NEXT TO ITEM 13.

For the respondent who volunteers that they were never in a situation that reminded them of the event, a code of "6" is provided. If any one of the symptoms is made worse by being reminded of the event, the answer is coded 5, even if most symptoms are not made worse.

PT43A-C — These are the familiar severity questions that are usually in the PFC. Note that they are asked about the problems taken together following EACH TRAUMATIC EVENT.

EXAMPLE: (for the respondent described in PT42):

PT43 I: Did you tell a doctor about the problems you had after you were assaulted?

R: No.

A I: CODE 1 IN COLUMN 1 OPPOSITE ITEM 5 AND ASK A. Did you tell any other professional about these problems you had after being assaulted?

R: Yes, I told my social worker.

B I: CODE 5 IN COLUMN II OPPOSITE ITEM 5 AND ASK B. Did you take medication more than once because of the problems you had after being assaulted?

R: No.

C I: CODE 1 IN COLUMN III AND ASK C. Did the problems you had after you were assaulted interfere with your life or activities a lot?

R: No.

PT43 I: CODE 1 IN COLUMN IV AND GO TO NEXT CIRCLED NUMBER, REPEATING PT43. Did you tell a doctor about the problems you had after being in the flood?

R: Yes, I did mention it while I was seeing him for the cold I got from wading in the flood water.

I: CODE 5 IN COLUMN I OPPOSITE ITEM 13 AND ASK B, AND C, SKIPPING A.

PT43B Medications can be over-the-counter or prescribed.

PT44 If the respondent cannot recall his age at the time of the event, code 98.

PT45 The question is asked about the first event circled and its onset is coded before asking about the next event.

PT46 This question assesses the duration of symptoms related to the traumatic event from the first to the most recent experience. If the respondent never had problems from (EXAMPLE) at least a few times a week, a code "never that often" is provided.

EDIT DECISIONS FOR PTSD

PROBLEM: Is divorce coded a #17 or #19?
DECISION: Code #19, not a sudden event.

PROBLEM: R. said he took aspirin for headache caused by problems. Does this count or do we use proximal cause?
DECISION: It does not count because proximal cause for taking meds. was headache not PTSD problems.

PROBLEM: Are illicit drugs counted as "self" meds.?
DECISION: Yes. All drugs are meds.--especially if R. intended them for self meds.
Decision Revised: No, unless they are drugs that would be used to control symptoms, i.e., Valium and other barbiturates.

PROBLEM: R. said military training (AIT) caused him PTSD. Code as combat or other trauma?
DECISION: Code under other trauma, not combat.

PROBLEM: What to do with multi-combat experiences?
DECISION: Code as combat (1), combat (2), and other trauma (17) or (18). This will facilitate age differences and narrow down times symptoms began and lasted.

PROBLEM: How to code "how soon after--did symptoms occur" when R. had symptoms throughout entire combat but does not know when symptoms began?
DECISION: If it was generalized combat and no specific incident, get R. to narrow down from time he was in the situation that caused his problems to when those problems became apparent to R.

PROBLEM: R. said he had trouble sleeping (PT38) and had taken meds. more than once (PT43) due to pain from a shooting incident. How to code?
DECISION: Code (1). We are looking for emotional rather than physical causes. Also ruled out because pain is the proximal cause, not the incident itself.

1. Incident
2. Pain — Proximal Cause
3. Problem

PROBLEM: R.'s experience of feeling ashamed of still being alive was after drug rehabilitation. Is this a PTSD?
DECISION: No. Code under #19 for all drug related or medical problems. These are not PTSD types.

PROBLEM: How to code for too many PTSDs for the categories given, i.e., (3) combat experiences, etc.?
DECISION: Probe through entire section with each symptom as before, but you will end up coding only the MOST severe, while keeping track of all symptoms in the DIS booklet. SEVERITY CRITERIA: Code throughout section for ALL symptoms that are positive for PT35 and PT36. NEXT SEVERE: You must have at least 2 (5's) in PT37-42 for a given symptom to be coded. Thus, the most severe remain while the less severe are dropped.

PROBLEM: How to code for being in prison?
DECISION: Being in prison is not a PTSD, but events while in prison can cause PTSD. It does have to be a specific event.

PROBLEM: How to code if R. says event caused symptoms, but R. does not consider event to be "horrible"?
DECISION: Repeat question emphasizing horrible. If R. does not consider it to be horrible or terrible, code 1.

PROBLEM: R. experienced trouble sleeping due to father beating up on mother--family violence continually for 7 years. Does this count as horrible experience or is it coded 19?
DECISION: Domestic violence does not qualify as a traumatic event if it is a long-term chronic problem. It does not meet the criteria of sudden event. Code 19. If R. mentions a specific event (e.g., father stabbing mother), that event would qualify as traumatic.

PROBLEM: When PT35.B is coded 5, it is summarized in PT42 as a problem and is recency considered at end in PT47?
DECISION: Yes. PT35.B is summarized and recency must be consistent with last time any one of these problems occurred in PT47.

PROBLEM: R. learned of an unexpected death of a close friend during combat as he was leaving Vietnam. Do we code under unexpected death or under combat?
DECISION: Code under combat whatever related to combat.

PROBLEM: Can having your house robbed or burglarized fit as PTSD criteria?
DECISION: Yes.

PROBLEM: Is girlfriend's abortion considered a PTSD?
DECISION: No. Code 19.

General Information for all Sections-Edit Decisions

Issue: In general, and specifically in depression and mania, the words "some" and "several" mean more than one symptom. Therefore, during a worst spell, there must be more than one symptom.

Refers to all probes containing a 3. Revised from edit dec. on Q.27, original DIS.

PROBLEM: If diagnosis from MD is alcoholism or drug addiction, how to code?
DECISION: If there is a 3 in the probe, and it was always due to drug addiction or alcoholism, code 3.

Q.68
PROBLEM: Does telling an MD during medical testing at LMF count as a positive response for any probe?
DECISION: No. Since the problem was not serious enough to warrant visiting an M.D. before R. came here, it does not count.

Q.105 (Applies to all probes containing a "3")
PROBLEM: During probe, when asking if SX was ever the result of taking med., drugs, or alcohol, R. said "No-except for coffee." Does this count as drug?
DECISION: Yes. Caffeine in coffee counts as a drug in probing. Continue probe with "was SX always the result of taking medication, drugs, or alcohol such as caffeine in coffee?"

O. Comments by Respondent and Interviewer

Q.259 gives the respondent an opportunity to amplify the report of his problems in any way he sees fit. Often respondents discuss problems related to physical health, finances, or interpersonal problems with spouse or parent in response to this question. The interviewer should record whatever the respondent says in the spaces provided.

If there were any unusual aspects of the respondent's current status (e.g., intoxicated) or history that would help to explain the answers obtained, they should be summarized here.

INTERVIEWER OBSERVATIONS: QUESTIONS 260-263

These four observation questions are used in making the schizophrenia diagnosis.

Q.260 Neologisms are words invented by the respondent: "He is a babaglug" or "he hopstepped me" are examples. If the interviewer thinks words that the respondent has used might be foreign phrases or colloquialisms he is unfamiliar with, after the interview he should ask "While we were talking, you used a word that I am not familiar with. The word was _____. What does that mean?" The interviewer should record words, definitions, and language on the lines provided below Q.260.

Q.261 This asks the interviewer to judge whether the respondent's responses seemed to be logically coherent. Schizophrenics may string together sentences that the interviewer can see no connection between. An example would be: "Yes, I am afraid of heights. The devil is out to get you all the time. But I'm going to Philadelphia next month."

Q.263 Occasionally, a floridly hallucinating person will actually talk to his "voices" during the interview--interrupting himself to say, "Get out of here," "Leave me alone," "I did not do that," or other such remarks. This question is designed to provide a place to record such events.

Time Ended: The interviewer enters the time the interview was completed in the box. He or she should remember to adjust the time if there was an interruption, so that the difference between the time on page 1 and the time entered here reflects the actual duration of the interview.

TABLE 1: DSM-III DIAGNOSES MADE BY DIS, VERSION III-A

| DIS VARIABLE | DSM-III DIAGNOSES COVERED (IN ORDER OF THEIR APPEARANCE IN DSM-III) |
|---|---|
| | Substance Use Disorders: |
| DSMALC | Alcohol abuse |
| | Alcohol dependence |
| TOBACCO | |
| DSMSCHIZ | Schizophrenic Disorders |
| DSMSZFRM | Psychotic Disorders Not Elsewhere Classified |
| | Schizophreniform disorder |
| | Major Affective Disorders: |
| DSMMANIA | Manic episode |
| DSMDEP | Major depressive episode |
| DSMBIPOL | Bipolar disorder |
| | Major Depression: |
| DSMDEPSE | Major depression, single episode |
| DSMDEPRT | Major depression, recurrent |
| | Other Specific Affective Disorders: |
| DSDYSTHY | Dysthymic disorder |
| | Atypical Affective Disorders: |
| DSMBIPII | Atypical Bipolar Disorder |
| DSMPHOB | Phobic Disorders (or Phobic Neurosis) |
| DSMSOCPH | Social phobia |
| DSMSMPPH | Simple phobia |
| | Anxiety States (or Anxiety Neuroses): |
| DSMPANIC | Panic disorder |
| DSGENANX | Generalized anxiety disorder |
| DSMOBCOM | Obsessive compulsive disorder |
| DSMPTSD | Post-traumatic stress disorder |
| DSMPTSD | Post-traumatic stress disorder, acute |
| DSMPTSD | Post-traumatic stress disorder, chronic or delayed |
| | Somatoform Disorders: |
| DSMSOM | Somatization disorder |
| | Gender Identity Disorders: |
| DSMTRSEX | Transsexualism |

| | |
|---|---|
| SEXDYSFN | Psychosexual Dysfunctions |
| | Other Psychosexual Disorders: |
| DSMHOMO | Ego-dystonic homosexuality |
| | Disorders of Impulse Control Not Elsewhere Classified |
| GAMBLING | Pathological gambling |
| | Personality Disorders |
| DSMASP | Antisocial personality |

TABLE OF CONTENTS

V. Psychological Examination Manuals

C. Results Interview, Psychology

1. Purpose

The results interview concerning psychological assessment will be conducted at the hotel on the day after psychological tests are completed. These meetings have several purposes.

a. Evaluate the reliability of each of the psychological tests administered to the participants (e.g., whether test scores can be explained by aphasia, physical disability, attentional deficits, poor cooperation, etc.).

b. Inform the veteran of any preliminary findings in the psychological and neuropsychological testing that might indicate a need for further evaluation and follow-up.

c. Provide the veteran with an opportunity to ask questions about the psychological and neuropsychological portion of testing.

d. Participants will be asked to sign a form which summarizes the recommendations, if any, made by the clinical psychologists.

e. Provide feedback about the experience to the interviewers. Relevant comments, concerns, and questions expressed by the participants will be compiled by the interviewing psychologists and communicated to the Chief Neuropsychologist and the other members of the psychology team at regularly scheduled meetings, or sooner if corrective action is indicated. These comments will be mailed to CDC on a monthly basis.

2. Personnel

a. Chief Neuropsychologist. Has the responsibility for overseeing the debriefing for this study. The clinical psychologists are responsible to the chief neuropsychologist and final policy decisions will be made by the chief neuropsychologist. The chief neuropsychologist will also conduct results interviews on a limited basis.

b. Clinical Psychologists. Professionals performing the results interviews are to be Ph.D. level psychologists, certified in the State of New Mexico. New Mexico does not license psychologists but certification requirements are comparable to licensing requirements in other states. Two psychologists have been hired 20 hours per week and one has been hired 10 hours per week. Members of the psychological results interview team have received specialized training in interpretation of the test data that will be available to them at the time of the interview. The clinical psychologists are expected to be

knowledgeable about personality assessment, psychiatric diagnosis and the complete neuropsychological testing battery used in this study. They also may be called upon to assist the Chief Neuropsychologist in the training and supervision of the neuropsychological technicians.

c. Follow-up Specialists. Two professionals with masters degrees in social work or counseling have been hired to assist participants in locating follow-up psychological or psychiatric care if they want such assistance. These services will be offered at the results interview and later phone requests will also be honored. The follow-up specialist will briefly interview the participant to identify what are appropriate services for further evaluation of his concerns (e.g., Vet Center, family counseling, individual psychotherapist) and the geographical area convenient to him. The specialist will contact services available in the area to get information about fees, waiting lists, etc. The participant will not be identified to the agency nor will an appointment be made; the information about services will be reported to the veteran by phone, and he will be responsible for further contact with the agency, counselor, etc.

3. Training of Staff

a. Psychologists will participate in technician training sessions to the extent that is necessary to become familiar with the test battery. Prior to the study, they will be familiar with the reference materials listed below and will have served as subjects in testing to gain firsthand experience with the tests and to gain some sensitivity to the participant's experience. In addition, they have had six hours of training in brain-behavior relations with Drs. Haaland and Yeo, with emphasis upon aphasia, spatial deficits, and attentional disorders. Videotapes and sample test results were used to illustrate these problems. These training sessions have been videotaped and will be available for additional staff training as needed.

b. The technician training manual and the DIS Training Manual will be included with this manual as references. In addition, the following texts are available to each psychologist and have been used in formulating the norms and procedures for reviewing the test results:

(1) Duckworth J. MMPI interpretation manual for counselors and clinicians. Muncie, Indiana: Accelerated Development, 1979.

(2) Greene RL. The MMPI, an interpretive manual. Orlando, Florida: Harcourt Brace Jovanovich, 1980.

(3) Lachar D. The MMPI: clinical assessment and automated interpretation. Los Angeles: Western Psychological Services, 1985.

(4) Lezak MD. Neuropsychological assessment. New York: Oxford University Press, 1983.

(5) Webb JT, McNamara KM, Rogers DA. Configural interpretations of the MMPI and CPI. Columbus, Ohio: Psychology Publishing, 1983.

(6) In addition, unpublished MMPI norms based on a male Veteran's Administration population will be used (Dr. Robin Morris, CDC consultant, personal communication).

4. Quality Control

a. Group Meetings

(1) Results interviewers will meet formally twice per week during Phase I (pilot test phase), once per week during Phase II (main study phase) and as needed throughout the remainder of the study. These meetings will deal with issues in maintaining consistency across interviewers, providing feedback to the technical staff, and documenting participant responses which will be sent to the Centers for Disease Control once a month. These meetings will also be used to discuss any problems with the debriefing process and to institute changes if necessary. It is expected that most changes will be made as a result of experience during Phase I.

(2) Results interviewers will maintain a log containing the participant code number, date, and time of each results interview. During Phase I, they will record questions asked by participants. The original of each participant's two-part acknowledgment of interview and request for release of information will be retained with the folder of psychological tests.

b. After the Interview

(1) Handling Interview Records
Medical records folders containing the participants' raw data will be returned to the Participant Advocate upon completion of the day's interviews. Under no circumstances will psychologists retain a participant's raw data longer than the day he is interviewed. The Participant Advocate will take the data to Medical Records.

(2) Follow-up
Psychologists will not be directly responsible for follow-up of any participant. However, a "record of recommendation," signed by the psychologist and the participant, will be retained. A follow-up specialist will be available to assist a participant who desires help in locating further psychological evaluation.

(3) Release
Records of results will be sent at the participant's request to health care professionals with an explanation. Except in exceptional cases a participant will not receive a written summary of results.

5. Procedure

a. Subjects
Participants in this study are Vietnam-era veterans recruited by CDC. They will have undergone medical and psychological evaluation for the two days prior to the results interview. They are described in the Psychology Manual for this study.

b. Scheduling
Scheduling of results interviews will be performed by the logistics staff. Participants will be scheduled for 20-minute interviews in one-hour blocks of six individuals. Two psychologists will be available for results interviewing. This scheduling system is designed to be compatible with the medical interview schedule for which three physicians are available for 30-minute results interviews.

c. Setting and Materials
Results interviews will be conducted in a private office at the hotel in which the participants are housed. Furnishings will include a desk, two chairs and the reference materials previously listed. Forms include:

(1) A copy of the medical history

(2) A folder of test results containing all test forms compiled by technicians

(3) Results Interview Validity Form

(4) Two-part Acknowledgment of Interview

(5) A copy of this manual

6. Interview

a. Prior to meeting with the participant, the psychologist will review the Minnesota Multiphasic Personality Inventory and the psychology technician's comments on the Interview Validity Form.

b. At the time of interview, participants will be greeted using their appropriate title and surnames.

(1) The participant will be told that the interview will be 15-20 minutes long and the purpose of the interview will be stated:

(a) To discuss any problems that may have occurred during the neuropsychological testing in order to specify reliability of the results. This discussion will be used to complete the Validity Form (Appendixes I and II) and the participant will be questioned directly about the technician's comments with reference to the different codes for rating invalidity/reliability (Appendixes III and IV). Based on technician comments and discussion with the participant, the psychologist will specify whether performance on individual tests should be considered valid or invalid. The psychologist will be blind to cohort membership, and this will be noted if broken.

(b) To inform the participant of the preliminary results of psychological and neuropsychological tests.

(c) To make recommendations about seeking further evaluation and follow-up (Appendixes V and VI).

(d) To provide an opportunity for the participant to ask questions and make comments regarding his experience with the psychological testing.

(2) The two-part acknowledgment of interview (Appendix V) will be signed by the psychologist and participant. The original will be retained by the psychologist and a copy of it will be given to the participant acknowledging that the interview was conducted. Recommendations provided to the participant may include reference to an identified problem area, but the psychologist will use professional judgment concerning the manner in which problem areas will be discussed.

(3) In addition, it will be stressed that the results being discussed are <u>preliminary</u> findings only and that no psychiatric or neuropsychological diagnosis will be made. Early in Phase II participants will be told that they will be asked if they are available to be contacted if further evaluation of their individual tests indicates incomplete

results (i.e., DIS data retrieval); however, this task will be performed by the technician administering the DIS thereafter. It will be important to make the distinction between identifying problem areas and making psychiatric diagnoses because the medical results interviewing team will, in fact, have sufficient data available to make diagnoses, while the psychological results interviewers will not.

(4) The MMPI profiles will be evaluated by first determining if the profile is valid or invalid as designated in MMPI Codes (Appendix VII). If the profile is valid, according to those criteria, elevations will be noted and evaluated according to Appendix VII. One, two and three point codes only will be assigned to each profile. Only profiles matching the codes in Appendix VII will be interpreted. Appendix VIII indicates what problem areas are associated with each code. For example, problems in the areas of depression and anxiety are associated with a 2-4-7 code. After the MMPI has been coded, the psychologist will use additional data to formulate a more complete clinical impression and to make the appropriate referral(s). Appendix VIII describes the sources of information which the psychologists will use in formulating clinical impressions. For example, if the MMPI has indicated that depression is a problem area, the psychologist will use the participant's self-report, medical history and observation by staff to make decisions about the referral. The psychologist will use lay language and adhere to standard clinical practices in explaining the reasons for referral to the participant. After the psychologist has discussed each problem area with the participant, a written recommendation will be given to the participant if warranted.

(5) Results interviewer will inform the participant about any need for further evaluation (Appendix VI). Each participant will be asked to sign the results interview form, noting that he was informed of the preliminary results of the evaluation (Appendix V).

7. Emergency Procedures

a. Medical Emergencies

Psychologists will be trained in CPR. In case of a medical emergency appropriate interim procedures will be employed and emergency medical personnel will be sent for.

b. Psychiatric Emergencies

(1) Psychiatric emergencies are defined as situations in which the participant is a danger to himself or others. Because

the test protocols do not, in the opinion of CDC, contain direct inquiries which would elicit information about danger to life, it is expected that any information concerning these risks which require action by the psychology staff will come to our attention apart from the data collection itself. This could happen either during psychological testing at Lovelace or during results interviewing at the hotel. Because the staff member receiving the information and the professional personnel qualified to perform an emergency evaluation will vary depending on the location, two different procedures are outlined.

(2) At Lovelace Medical Center, a technician administering the tests is the most likely recipient of information needing emergency evaluation. If the technician is concerned about the issues of potential harm to self or harm to others, he/she will consult with a CDC staff psychologist or the head neuropsych technician. If evaluation is warranted, the Project Director will be notified and assessment will be performed by a qualified clinical psychologist on our research staff or by a member of Lovelace's Mental Health Department. The clinician performing the evaluation will recommend immediate hospitalization if necessary. If notification of others is required (e.g., threat to life), the Project Director and Chief Neuropsychologist will be informed and action will be taken. If the participant will be able to return safely to his home community, the Follow-up Specialist will assist in arranging services.

(3) At the hotel, if the clinical psychologist is concerned about a participant's safety or other risk to life, he/she will perform a clinical evaluation as soon as possible. Results of this evaluation will be communicated to the Project Director and the Chief Neuropsychologist. Immediate hospitalization in Albuquerque may be recommended. If notification of others is necessary (e.g., threat to life), action will be taken. If the participant will be able to return safely to his home community, the Follow-up Specialist will assist in arranging services.

c. Legal Emergencies

The only other emergency for which we can anticipate a need for immediate action by a staff psychologist is child abuse. This may be witnessed by the psychologist in a case where a participant is accompanied by his family or revealed in the course of evaluation and/or interview. In such a case the psychologist will report the interview findings to the Chief Neuropsychologist. The Chief Neuropsychologist will then inform the Project Director and a qualified clinical psychologist, either a member of the study staff or a member of the Mental Health Department of Lovelace Medical Center. The participant

will be asked to attend an evaluation session with the psychologist. The results of this clinical evaluation will determine whether or not it is considered necessary for protective services to be notified. The Veterans' Health Study Project Director and Chief Neuropsychologist will be informed about any recommendations made by the clinical psychologist. Reports will be made to the Bernalillo County Child Protection Services and their usual procedures will be followed for notifying the child protective agency in the participant's home community.

8. Appendix I - Psychology Results Interview - Individual Tests (Validity)

| | | | | |
|---|---|---|---|---|
| 1. | EXAM CODE | | /P/I/Q/1/ | (0001-0004) |
| 2. | Participant ID | | /_/_/_/_/_/_/_/ | (0005-0011) |
| 3A. | Participant Name_____ | | | |
| 3B. | Participant Sequence No. | even_____ odd_____ | | |
| 4. | Date | Month | /_/_/ | (0012-0013) |
| | | Day | /_/_/ | (0014-0015) |
| | | Year | /_/_/ | (0016-0017) |
| 5. | Time of Results Interview | Hour | /_/_/ | (0018-0019) |
| | | Min | /_/_/ | (0020-0021) |
| 6. | Psychologist ID | | /_/_/_/ | (0022-0025) |
| | | | /9/9/9/9/ | (0026-0029) |

Technicians: Please use the comment section to enter any observations that could influence results.

Psychologists: Please code up to 3 items that could influence results.

If you consider the test to be valid, put '01' in the 'lst' code area only. Validity codes are listed on the last page of this form.

TESTS

8. WRAT (reading)

_____
_____ : lst /_/_/ (0030-0031)

_____
_____ : 2nd /_/_/ (0032-0033)

_____
_____ : 3rd /_/_/ (0034-0035)

CVLT (California Verbal Learning Test) :

9. Immediate Recall

_____
_____ : lst /_/_/ (0036-0037)

_____
_____ : 2nd /_/_/ (0038-0039)

_____
_____ : 3rd /_/_/ (0040-0041)

10. Delayed Recall

_____
_____ : lst /_/_/ (0042-0043)

_____
_____ : 2nd /_/_/ (0044-0045)

_____
_____ : 3rd /_/_/ (0046-0047)

Grooved Pegboard

11. Right Hand

_____
_____ : lst /_/_/ (0048-0049)

_____
_____ : 2nd /_/_/ (0050-0051)

| | | | |
|---|---|---|---|
| | _____ | | |
| | _____ | 3rd /_/_/ | (0052-0053) |
| | | | |
| 12. | **Left Hand** | | |
| | _____ | | |
| | _____ | 1st /_/_/ | (0054-0055) |
| | _____ | | |
| | _____ | 2nd /_/_/ | (0056-0057) |
| | _____ | | |
| | _____ | 3rd /_/_/ | (0058-0059) |
| | | | |
| WAIS-R | | | |
| | | | |
| 13. | **Information** | | |
| | _____ | | |
| | _____ | 1st /_/_/ | (0060-0061) |
| | _____ | | |
| | _____ | 2nd /_/_/ | (0062-0063) |
| | _____ | | |
| | _____ | 3rd /_/_/ | (0064-0065) |
| | | | |
| | | | |
| 14. | **Block Design** | | |
| | _____ | | |
| | _____ | 1st /_/_/ | (0066-0067) |
| | _____ | | |
| | _____ | 2nd /_/_/ | (0068-0069) |
| | _____ | | |
| | _____ | 3rd /_/_/ | (0070-0071) |
| | | | |
| Rey-Osterrieth | | | |
| | | | |
| 15. | Copy | | |
| | _____ | | |
| | _____ | 1st /_/_/ | (0072-0073) |
| | _____ | | |
| | _____ | 2nd /_/_/ | (0074-0075) |

| | | | |
|---|---|---|---|
| | _____ | | |
| | _____ | 3rd /__/__/ | (0076-0077) |
| 16. | Immediate Recall | | |
| | _____ | | |
| | _____ | 1st /__/__/ | (0078-0079) |
| | _____ | | |
| | _____ | 2nd /__/__/ | (0080-0081) |
| | _____ | | |
| | _____ | 3rd /__/__/ | (0082-0083) |
| 17. | Delayed Recall | | |
| | _____ | | |
| | _____ | 1st /__/__/ | (0084-0085) |
| | _____ | | |
| | _____ | 2nd /__/__/ | (0086-0087) |
| | _____ | | |
| | _____ | 3rd /__/__/ | (0088-0089) |
| 18. | Wisconsin Card Sort | | |
| | _____ | | |
| | _____ | 1st /__/__/ | (0090-0091) |
| | _____ | | |
| | _____ | 2nd /__/__/ | (0092-0093) |
| | _____ | | |
| | _____ | 3rd /__/__/ | (0094-0095) |
| 19. | Word List Generation (FAS) | | |
| | _____ | | |
| | _____ | 1st /__/__/ | (0096-0097) |
| | _____ | | |
| | _____ | 2nd /__/__/ | (0098-0099) |
| | _____ | | |
| | _____ | 3rd /__/__/ | (0100-0101) |

| | | | |
|---|---|---|---|
| 20. | PASAT (Paced Auditory Serial Addition Test) | | |
| | _____ | | |
| | _____ | 1st /__/__/ | (0102-0103) |
| | _____ | | |
| | _____ | 2nd /__/__/ | (0104-0105) |
| | _____ | | |
| | _____ | 3rd /__/__/ | (0106-0107) |
| 21. | DIS (Diagnostic Interview Schedule) | | |
| | _____ | | |
| | _____ | 1st /__/__/ | (0108-0109) |
| | _____ | | |
| | _____ | 2nd /__/__/ | (0110-0111) |
| | _____ | | |
| | _____ | 3rd /__/__/ | (0112-0113) |
| 22. | Combat Exposure Index | | |
| | _____ | | |
| | _____ | 1st /__/__/ | (0114-0115) |
| | _____ | | |
| | _____ | 2nd /__/__/ | (0116-0117) |
| | _____ | | |
| | _____ | 3rd /__/__/ | (0118-0119) |
| 23. | Results Interview | | |
| | _____ | | |
| | _____ | 1st /__/__/ | (0120-0121) |
| | _____ | | |
| | _____ | 2nd /__/__/ | (0122-0123) |
| | _____ | | |
| | _____ | 3rd /__/__/ | (0124-0125) |

VALIDITY CODES FOR DEBRIEFING

01 = OK (VALID)
02 = APHASIA
03 = PROFOUND MOTOR IMPAIRMENT
04 = SEVERE ATTENTIONAL DISORDER
05 = PROFOUND HEARING LOSS
06 = PROFOUND VISUAL PROBLEMS
07 = ILLITERACY
08 = INTOXICATION OR SIGNIFICANT SUBSTANCE ABUSE
09 = BLANK
10 = PHYSICAL ILLNESS
11 = BIZARRE PERFORMANCE
12 = PROFOUND FATIGUE
13 = MINIMAL COMPLIANCE
14 = SEVERE CONFUSION
15 = ADMINISTRATION ERROR
16 = ENVIRONMENTAL INTERFERENCE
17 = NON-ENGLISH SPEAKING
18 = NON-STANDARD ADMINISTRATION
19 = AMPUTATION
20 = ACUTE INJURY
98 = DON'T KNOW
99 = REFUSED

9. Appendix II - Psychology Results Interview - Group Tests (Validity)

| | | | | |
|---|---|---|---|---|
| 1. | EXAM CODE | | /P/G/0/1/ | (0001-0004) |
| 2. | Participant ID | | / / / / / / / / | (0005-0011) |
| 3. | Participant Name_____ | | | |
| 4. | Date | Month | / / / | (0012-0013) |
| | | Day | / / / | (0014-0015) |
| | | Year | / / / | (0016-0017) |
| 5. | Time of Results Interview | Hour | / / / | (0018-0019) |
| | | Min | / / / | (0020-0021) |
| 6. | Psychologist ID | | / / / / / | (0022-0025) |
| | | | /9/9/9/9/ | (0026-0029) |

Technicians: Please use the comment section to enter any observations that could influence results.

Psychologists: Please code up to 3 items that could influence results. If you consider the test to be valid, put '01' in the 'lst' code area only. Validity codes are listed on the last page of this form.

| TESTS | | Validity Codes | |
|---|---|---|---|
| 8. | Army Classification Battery | | |
| | _____ | | |
| | _____ | 1st / / / | (0030-0031) |
| | _____ | | |
| | _____ | 2nd / / / | (0032-0033) |

| | | | |
|---|---|---|---|
| | _____ | : | |
| | _____ | : 3rd / / / | (0034-0035) |
| | | : | |
| 9. | MMPI | : | |
| | _____ | : 1st / / / | (0036-0037) |
| | _____ | : | |
| | _____ | : 2nd / / / | (0038-0039) |
| | _____ | : | |
| | _____ | : 3rd / / / | (0040-0041) |
| | | : | |
| 10. | Handedness | : | |
| | _____ | : | |
| | _____ | : 1st / / / | (0042-0043) |
| | _____ | : | |
| | _____ | : 2nd / / / | (0044-0045) |
| | _____ | : | |
| | _____ | : 3rd / / / | (0046-0047) |
| 11. | Combat Exposure Index | : | |
| | _____ | : | |
| | _____ | : 1st / / / | (0048-0049) |
| | _____ | : | |
| | _____ | : 2nd / / / | (0050-0051) |
| | _____ | : | |
| | _____ | : 3rd / / / | (0052-0053) |
| | | : | |

VALIDITY CODES FOR DEBRIEFING

01 = OK (VALID)
02 = APHASIA
03 = PROFOUND MOTOR IMPAIRMENT
04 = SEVERE ATTENTIONAL DISORDER
05 = PROFOUND HEARING LOSS
06 = PROFOUND VISUAL PROBLEMS
07 = ILLITERACY
08 = INTOXICATION OR SIGNIFICANT SUBSTANCE ABUSE
09 = BLANK
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11 = BIZARRE PERFORMANCE
12 = PROFOUND FATIGUE
13 = MINIMAL COMPLIANCE
14 = SEVERE CONFUSION
15 = ADMINISTRATION ERROR
16 = ENVIRONMENTAL INTERFERENCE
17 = NON-ENGLISH SPEAKING
18 = NON-STANDARD ADMINISTRATION
19 = AMPUTATION
20 = ACUTE INJURY
98 = DON'T KNOW
99 = REFUSED

10. Appendix III - General Explanation of Validity Codes

Codes 2 through 7 and 17 through 20 refer to disabilities which may interfere with specific tests. For example, illiteracy can invalidate tests which require reading whereas it would have no bearing on drawing tests (e.g., Rey-Osterreith Complex Figure). Codes 8-16 and 18 refer to conditions which could have an impact on any test in the battery.

(1) 01 = VALID

(a) For every individual, the object of testing is to get an index of optimal performance, and the invalidity codes will specify the basis for less than optimal performance. For example, for the Army Classification Battery to be coded valid there can be no evidence of aphasia to prevent understanding of auditory instructions and reading, profound motor impairment to prevent filling out the answer sheet, severe attentional disorder to prevent completing the test in the allotted time or profound visual problems to prevent reading. Intoxication or significant substance abuse, refusal, physical illness, bizarre performance, profound fatigue, minimal compliance, severe confusion, administration error, and environmental interference could all produce less than optimal performance in a participant and could be the basis of an invalid rating.

(b) This is the most frequently used code. It is used when effort, alertness, and cooperation were adequate. Behavior was appropriate and there was no evidence of a problem which would affect the specific test being coded.

(2) 02 = APHASIA (expressive or receptive language disorder)

Use this code when expressive or receptive language difficulties interfere with testing. Except for the reading test (WRAT) and Word List Generation, there are no tests in the battery designed specifically to assess aphasia. The results of the WRAT will be available for the results interview and specifying validity codes. For the purpose of specifying validity, expressive aphasia will be judged on the basis of spontaneous speech, and the etiology of the problem will not be considered (i.e., acquired and developmental aphasias would both be the basis of invalid ratings). If the participant's speech is halting, telegraphic, characterized by poor articulatory agility with short phrase length or there is evidence of paraphasic errors or neologisms, or verbal apraxia, expressive aphasia

will be considered a problem. However, it is only when this problem affects the participant's ability to answer questions on tests which do not evaluate aphasia that it will be the basis of an invalid code. Auditory comprehension problems or a receptive aphasia will also be based on observation. If the participant requires a large number of repetition of instructions not due to hearing difficulties and sometimes is not able to understand the instructions, that would be a basis for an invalid rating for those tests which are affected. For example, the Wisconsin Card Sort might be significantly affected by auditory comprehension deficits while the Rey-Osterrieth Complex Figure is less likely to be affected by this particular problem.

(3) 03 = PROFOUND MOTOR IMPAIRMENT

This code should be used when hand function is so impaired that the subject cannot complete the test. The impairment will have greater influence on a motor test such as the Grooved Pegboard Test, but the basis for using the code will be that the technician will attempt the test and find the participant cannot perform it. Impairment of the dominant hand will have the greatest general impact because it could potentially affect any of the tests which require movement (e.g., Rey-Osterrieth Complex Figure, Block Design). Motor impairment may be bilateral or unilateral; if it is unilateral, the subject can use his unaffected hand, and most results will be valid. Acute injury which temporarily disables hand function should be coded 20.

(4) 04 = SEVERE ATTENTIONAL DISORDER

This code will be used when attentional disorders seem to have interfered with information processing, and attention is not being measured by that test. For instance, low PASAT scores in an individual with attentional difficulties would not be invalid, whereas low scores on a task like the Rey Figure based on this factor may be invalid. The basis for this designation would be observations such as extreme distractibility reflected in attention to extraneous stimuli, frequent need to repeat with comments of "I was drifting off"; "I missed that, my mind was somewhere else." Long latency responses not obviously associated with concentration or thinking about the test would also be the basis for this code.

(5) 05 = PROFOUND HEARING LOSS

Use this code for language tests when auditory impairment even with correction is so severe that the subject could not hear language even when it was delivered at loud

volumes. This code does not apply when hearing aids enable the subject to hear adequately. For instance, WAIS-R Information, California Verbal Learning, PASAT, and DIS cannot be administered to a severely hard-of-hearing individual. Word List Generation and Wisconsin Card Sort can sometimes be administered. Consider in all cases where hearing impairment is an issue whether the individual can lip-read well enough to perform tests.

(6) 06 = PROFOUND VISUAL PROBLEMS

Use this code for tests which have necessary visual information the subject cannot perceive at any distance. The Rey-Osterrieth Complex Figure, WAIS-R Block Design, Wisconsin Card Sort, Grooved Pegboard, and WRAT-Reading cannot be validly administered to a blind person. Tunnel vision, field cuts or other conditions of partial sightedness do not rule out valid tests with visual input. Note that the Wisconsin Card Sorting Test requires color discrimination and some color blind individuals may not be able to perform this test.

(7) 07 = ILLITERACY

Use this code for tests which require reading but do not assess literacy. An illiterate will usually have difficulty with Word List Generation because of unfamiliarity with spelling and phonetics. For the MMPI reading level below upper 6th grade is the index of illiteracy; however, for other tests a lower level may be appropriate (e.g., Word List Generation may require only a 3rd grade reading level).

(8) 08 = INTOXICATION OR SIGNIFICANT SUBSTANCE ABUSE

(a) Use this code when breath alcohol levels indicated intoxication (>0.05) or when physical or behavioral signs of drug or alcohol use were noted by the technician. It can apply to any test. Signs of drug or alcohol intoxication include the following: slurred speech, unsteady gait, bloodshot eyes, dilated pupils.

(b) The breath alcohol tests will be administered after lunch to participants who "failed" it in the morning. It is possible that a subject who "failed" the BAT in the morning will no longer be intoxicated by the afternoon.

(9) 10 = PHYSICAL ILLNESS

Use this code when the subject acted ill or complained of illness during a test, or became acutely ill requiring

medical attention. It can apply to any test but does not necessarily invalidate the entire battery.

(10) 11 = BIZARRE PERFORMANCE

Use this code when the technician has observed bizarre behavior suggestive of hallucinations or delusions or there is strong evidence of a thought disorder which appears to have interfered significantly with test performance. Use of neologisms (without evidence by history and other testing of receptive aphasia) or slang associations in speech, inappropriate drawings on drawing tasks, or blocking are examples that suggest this code.

(11) 12 = PROFOUND FATIGUE

Use this code when the technician has observed behaviors like falling asleep, very frequent yawning, or significant complaints about fatigue, and these appear to have interfered with performance. This code can be applied to any test.

(12) 13 = MINIMAL COMPLIANCE

Use this code when the participant did not refuse a task outright but performed it perfunctorily or flippantly, often with complaints about its irrelevancy or excessive difficulty. There may be inappropriate invectives or abusive language.

(13) 14 = SEVERE CONFUSION

Use this code when the subject appeared unable to comprehend test instructions or tasks. It would occur in cases of severe mental deficiency or organicity. It should not be used if it appeared that instructions were understood and a meaningful effort was made, however defective the product. It may be difficult to differentiate this code from intoxication and bizarre behavior. Intoxication would take precedence over this code if breath alcohol levels were over 0.05; bizarre behavior would take precedence over this code if clinical impression and personality inventories were consistent with its presence.

(14) 15 = ADMINISTRATION ERROR

Use this code when the technician has made an error which affected the test results; for instance, mistakes on timing a task or exposure of stimuli. Results of the test should be considered before applying this code because some administrative errors are minor (e.g., delay of longer than 20 minutes on the Rey or CVLT).

(15) 16 = ENVIRONMENTAL INTERFERENCE

Use this code when noise, interruptions, equipment malfunction, etc., occurred during a test and disrupted the participant's performance. It is of greater concern in speed and/or memory tasks (e.g., PASAT, Grooved Pegboard) than on tasks where these factors are not important (e.g., WAIS-R Information, WRAT-R Reading).

(16) 17 = NON-ENGLISH SPEAKING

This code is used for the rare participant who does not comprehend and/or speak English. For instance, California Verbal Learning, WRAT-R Reading, PASAT, and MMPI would not be valid if administered in English to a non-English speaking person. The Rey Complex Figure and Wisconsin Card Sort are examples of tests which could usually be administered with instructions translated.

(17) 18 = NON-STANDARD ADMINISTRATION

This factor does not necessarily invalidate a test, although it may. It would be coded if the technician intentionally, for some reason such as maintaining rapport or interest, varied the method of test administration.

(18) 19 = AMPUTATION

Use this code when amputation of one or both upper limbs interferes with performance on a task with a manual component (i.e., Rey, Block Design, Grooved Pegboard, ACB). The Wisconsin Card Sort, MMPI and CEI can be administered with the examiner performing necessary manipulations of materials and filling out answer sheets without compromising validity of the tests.

(19) 20 = ACUTE INJURY

Use this code when the participant complains of recent injury which affects performance on a test. Examples are hand injury affecting manual skill, eye infection causing blurry vision, oral/dental problems making speech painful or difficult.

(20) 99 = REFUSAL

Use this code when the technician indicated that the participant refused to take a test. It can apply to any test but does not invalidate the entire battery.

11. Appendix IV - Invalidity Codes: Individual Tests

(Codes 8 and 10 through 16 could occur for any of the tests, and the reason is obvious so it will not be specified for each test individually. Code 09 is reserved by the data analysis system and is not appropriate for the validity instrument. If any of the other codes are <u>not</u> included, that implies they cannot be used for that particular test.

(1) ARMY CLASSIFICATION BATTERY

(a) Aphasia.
Poor comprehension of auditory or written information.

(b) Profound Motor Impairment.
Prevents filling out answer sheet.

(c) Profound Visual Problems.
Prevents reading test forms and answer sheet.

(d) Attentional Problems.
Prevents participant from completing test in allotted time.

(e) Profound Hearing Loss.
Prevents comprehension of auditory instructions.

(f) Illiteracy and non-English speaking codes would appear to apply here; however, neither of these problems would have been acquired since the participant's induction; thus for comparison purposes they do not invalidate this test.

(2) WAIS-R INFORMATION

(a) Aphasia.
Could prevent understanding of questions and verbal responses depending if there was a receptive or expressive problem.

(b) Profound Hearing Loss.
Could prevent the participant from hearing questions and responding appropriately as a result.

(c) Non-English Speaker.
Would prevent comprehension of questions and a verbal response in English.

(3) CALIFORNIA VERBAL LEARNING TEST

(a) Aphasia.
Could affect the understanding of task instructions, understanding of the words in the lists to be remembered, and even the required verbal responses if expressive problems also exist.

(b) Profound Hearing Loss.
Would prevent understanding of auditory instructions as well as understanding of the individual items on the list.

(4) REY-OSTERRIETH COMPLEX FIGURE

(a) Aphasia.
Could prevent understanding of verbal instructions.

(b) Profound Motor Impairment.
Could affect drawing if the dominant hand is impaired.

(c) Profound Visual Impairment.
Could prevent vision of the design.

(5) PACED AUDITORY SERIAL ADDITION TEST

(a) Aphasia.
Could prevent understanding of auditory instructions, understanding of the numbers, and verbal responses.

(b) Profound Hearing Loss.
Could prevent understanding of auditory instructions and numbers.

(c) Illiteracy.
Could indicate that the participant can't perform the arithmetic manipulations necessary to do even a single track arithmetic task.

(d) Non-English Speaker.
Could prevent understanding of English instructions, understanding the numbers, and responding verbally.

(6) WAIS-R-BLOCK DESIGN

(a) Aphasia.
Could prevent comprehension of auditory instructions.

(b) Profound Motor Impairment.
Could prevent manipulation of blocks if motor impairment is bilateral.

(c) Profound Hearing Impairment.
This factor would affect the results of these tests only if the participant could not be made to understand the test instructions.

(d) Profound Visual Problems.
Could prevent adequate vision of the block designs.

(7) WORD LIST GENERATION

(a) Severe Attentional Disorder.
Could interfere with staying on task.

(b) Profound Hearing Loss.
Could interfere with perception of stimuli.

(c) Illiteracy.
May be associated with difficulty in spelling and phonics. An illiterate would have less difficulty with categories than with FAS.

(8) WISCONSIN CARD SORT

(a) Aphasia.
Receptive language disorder could affect comprehension of test instructions.

(b) Severe Attentional Disorder.
Could contribute to failure to stay on task and maintain set.

(c) Profound Visual Problems.
Prevents the participant from seeing the stimulus cards. Note that some cases of color blindness may involve difficulty making color discriminations.

(d) Profound Hearing Loss.
Could prevent the participant from understanding the instructions presented in any form.

12. Appendix V - Results Interview Signature Form

(1) Version used on or prior to 8/12/85

The psychological and neuropsychological tests which you took have provided some preliminary results which have been discussed with you. As you were told, this group of tests was organized as a research battery which does not lead to a specific diagnosis.

Although we do not expect to need to contact you after you leave Albuquerque, it is possible that we may require additional information. Are you available for further telephone contact?

YES_____
NO _____

If YES, phone number:_____

Address:_____

_____

Best time to call:_____

Suggestions:_____

_____

_____

_____

I acknowledge that these results have been communicated to me in language that I can understand and that I have received a copy of this form.

_____ Code No._____
Signature of Participant

_____ Date_____
Signature of Psychologist

(2) Version used after 8/12/85

The psychological and neuropsychological tests which you took have provided some preliminary results which have been discussed with you. As you were told, this group of tests was organized as a research battery which does not lead to a specific diagnosis.

Suggestions:_____

_____

_____

_____

I acknowledge that these results have been communicated to me in language that I can understand and that I have received a copy of this form.

_____ Code No._____
Signature of Participant

_____ Date_____
Signature of Psychologist

13. Appendix VI - Letter Concerning Psychological and Neuropsychological Test Results

Dear :

Mr. "Veteran", a participant in the Veterans Health Study at Lovelace Medical Center, has requested that you receive a report of his scores on psychological tests administered in the study. The group of psychological and neuropsychological tests administered in the study were chosen for their relevance to Agent Orange exposure and the Vietnam experience. They do not constitute a complete battery of psychological tests; consequently, a diagnosis cannot be made from them.

On the enclosed computer printout are scores for the following tests:

1. Wechsler Adult Intelligence Test-Revised (WAIS-R) Information subtest. This is a test of fund of general information. It is highly correlated with Verbal IQ, although it is significantly affected by formal education. Questions like "Who was Dizzy Gillespie?" and "At what temperature does water freeze?" are asked.

2. Army Classification Battery. This is a paper-and-pencil test of vocabulary and arithmetic reasoning skills. It is the same test the veteran took when he was inducted into the Army.

3. Wide Range Achievement Test, Reading. This is a test of reading recognition.

4. Word List Generation. This test measures ability to generate quickly words which are members of a given category, like "beginning with the letter e" or "kinds of fruits and vegetables."

5. WAIS-R Block Design subtest. This test measures visuospatial abstraction and conceptualization. It is highly correlated with Performance IQ.

6. Rey Complex Figure. This test requires copying a complex design and then drawing it from memory. It measures visuoconstructive skills and visuospatial memory.

7. Grooved Pegboard. This test measures speed at a manual assembly task with each hand.

Other tests which were administered are not reported here because their results have not been analyzed pending collection of group data. Scores on a participant's Minnesota Multiphasic Personality Inventory are available to

licensed psychologists and practitioners with equivalent training in MMPI interpretation. If you meet these criteria and would like your patient's MMPI profile, please send a release form on your letterhead.

Yours truly,

Elisabeth Elliott
Medical Records Specialist

EE/mkp

Enclosure

## 14. Appendix VII - Summary of Test Interpretations

### (1) MMPI CODES

The MMPI elevation codes listed below will be used as partial bases for formulating clinical impressions. These codes and criteria listed below are based on works of Lachar (1985), Greene (1980), and Webb et al. (1983). Any MMPI
reaching criterion level should be considered for appropriate clinical impressions.

| ELEVATION | PSYCHOT | DEP | MAN | ANX | PHYSIO | CHAR |
|---|---|---|---|---|---|---|
| 1 | | | | | X | |
| 1-2 | | X | | | X | |
| 1-2-3 | | X | | X | X | |
| 1-2-8 | X | | | | X | |
| 1-3 | | | | | X | |
| 1-3-4 | | | | | X | X |
| 1-3-7 | | | | X | X | |
| 1-3-8 | X | | | | X | |
| 1-3-9 | | | | | X | X (ck neuro) |
| 1-4 | | | | | X | X |
| 1-6 | | | | | X | |
| 1-7 | | | | X | X | |
| 1-8 | X | | | | X | |
| 1-9 | | | X | | X | |
| 2 | | X | | | | |
| 2-3 | | X | | | X | |
| 2-4 | | X | | | | |
| 2-4-3 | | X | | | | X |
| 2-4-7 | | X | | X | | |
| 2-4-8 | | X | | | | X |
| 4-8-2/2-6-8 | X | X | | | | |
| 2-6 | | X | | | | X |
| 2-6-4/2-6-8 | X | X | | | | X |
| 2-7 | | X | | X | | |
| 8-7-2/8-2-7/ 2-8-7 | X | X | | X | | |
| 2-8 | | X | | X | | |
| 8-2 | X | X | | X | | |
| 2-9 | | X | X | | | |
| 3-4 | | | | | | X |

| ELEVATION | PSYCHOT | DEP | MAN | ANX | PHYSIO | CHAR |
|---|---|---|---|---|---|---|
| 3-6 | | | | | | X |
| 3-7 | | | | X | X | |
| 3-8 | | | | | X | |
| 3-9 | | | X | | X | |
| 4-6 | | | | | | X |
| 4-6-8 | X | | | | | |
| 4-7 | | X | | | | X |
| 4-8 | X | | | | | |
| 4-9 | | | | | | X |
| 6-7 | | | | X | | X |
| 6-8 | X | | | | | |
| 6-9 | X | | X | | | |
| 7-8 | | | | X | | |
| 7-9 | | | X | X | | |
| 8-7 | X | | | X | | |
| 8-9 | X | | X | | | |

(2) Standard Criteria

(a) Minimum elevations for significance for single scales:

4 = 79 + T (Lachar, 1985)
6 = 79 + PSYCHOT  70 - 79T = CHAR (Lachar, 1985)

(b) All other scales = 70 (Lachar, 1985)

(c) Validity:

1. "?" = 31+ = invalid (Greene, 1980)
2. F = 90 + T = invalid (Greene, 1980)
3. Otherwise = valid

(3) VA Male Norms (Morris, personal communication, 1985)

The following norms are experimental. They represent t-scores which are 2 SD's above average in a recent study of VA patients.

| Scale | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 |
|---|---|---|---|---|---|---|---|---|---|---|
| t-score | 75 | 80 | 75 | 75 | 75 | 73 | 78 | 82 | 75 | 73 |

16. Appendix IX - Cognitive Components of Available Neuropsychological Tests

| COGNITIVE FUNCTION | TEST | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | ACB | WLG | PASAT | RCF | GP | WRAT | INFO | BD |
| School Achievement | XX | | | | | XX | XX | |
| Math | XX | | X | | | | | |
| Directed Attention | | | | XX | | | | XX |
| Planning | | XX | | XX | | | | X |
| Perception | | | | XX | | | | X |
| Visuo-construction | | | | XX | | | XX | |
| Visuo-motor integration | | | | X | XX | | | |
| Reading | XX | | | | | XX | | |
| Concentration/ Attention | X | XX | | XX | X | | | |
| Motor | | | | X | XX | | | |

ACB = Army Classification Battery
WLG = Word List Generation
PASAT = Paced Auditory Serial Addition Test
RCF = Rey Complex Figure
GP = Grooved Pegboard
WRAT = Wide Range Achievement Test (Reading)
INFO = WAIS-R Information
BD = WAIS-R Block Design

a. Neuropsychological Syndromes

(1) LEFT HEMISPHERE: math, reading, conc/att., motor (R)

(2) RIGHT HEMISPHERE: planning, visuo-constructive, perception, motor (L), directed attention

(3) FRONTAL LOBE: planning, visuo-motor integration, conc/att., motor (L+R)

(4) DEPRESSION: perception, conc/att., visuo-constructive skills, MMPI

(5) PARANOID SCHIZ: conc/attention, planning (?), MMPI

(6) OTHER SCHIZ: conc/attention, planning, visuo-motor integration, old school achievement, MMPI

(7) LEARNING DISABILITY: reading, math

(8) ANXIETY: conc/attention, math (?), planning, MMPI

(9) ALCOHOL: conc/attention, planning, visuo-construction skills, visuo-motor integration, MMPI (?), grooved pegboard (bilateral)

b. Interpretation of Patterns

(1) Is there deterioration?

(2) Any specific signs?

(3) Use patterns of test performance to derive pattern of cognitive deficits.

(4) Compare patterns of cognitive deficits to specific syndromes.

(5) Confirmation and emotional reaction by subjects.

15. Appendix VIII

a. Data Used for Formulation of Clinical Impression

This appendix describes the sources of information which the psychologists may use in formulating clinical impressions of the participants. Unless otherwise specified, each source of information listed under a particular category is sufficient to warrant the formulation of that particular clinical impression. The clinical impression would form the basis of a recommendation for further evaluation; however, it is not part of formal data collection for the study.

(1) Substance Abuse
    (a) Self Report
    (b) Observations by neuropsychological technicians, medical staff or psychologists.

(2) Psychotic Disorder
    (a) Self Report
    (b) Medical History
    (c) MMPI Data
    (d) Observations by staff (when accompanied by a, b, or c).

(3) Depression
    (a) Self Report
    (b) Medical History
    (c) MMPI Data
    (d) Observations by staff (when accompanied by a, b, or c).

(4) Mania
    (a) Self Report
    (b) Medical History
    (c) MMPI Data
    (d) Observations by staff (when accompanied by a, b, or c).

(5) Anxiety Disorder
    (a) Self Report
    (b) Medical History
    (c) MMPI Data
    (d) Observations by staff (when accompanied by a, b, or c).

(6) Post-Traumatic Stress Disorder
    (a) Self Report and/or Combat Exposure Index
    (b) Medical History
    (c) Observations by staff (when accompanied by a or b).

(7) Psychological Factors Interacting With Physical Condition
    (a) Self Report
    (b) Medical History
    (c) MMPI Data
    (d) Observations by staff (when accompanied by a, b, or c).

(8) Characterological Traits
    (a) Self Report
    (b) Medical History
    (c) MMPI Data
    (d) Observations by staff (when accompanied by a, b, or c).

TABLE OF CONTENTS

e. Confidentiality
f. Security
g. Unauthorized Use of Veterans' Health Study Vehicles
h. Problems
i. Emergency Situations
j. Equipment and Supplies
k. Quality Control

5. Participant Lodging

a. Objective
b. Procedures
c. Participant Transportation
d. Participant Hotel Registration and Checkout
e. Participant Meals at Hotel
f. Relatives or Guests of Participants
g. Incidental Charges Incurred by Participants
h. Cost Control
i. Veterans' Health Study Satellite Office
j. Security and Confidentiality
k. Enforcement
l. Logistics Management Contact With Lodging Facility Personnel
m. Equipment and Supplies
n. Problem Procedures
o. Quality Control

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

a. Objective
b. Early Arrival/Late Departure
c. Meals/Entertainment During Examination Period
d. Cash Provision
e. Auditing
f. Contingency Planning

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

a. Participant Phones Lovelace From His Home
b. Participant Phones While Enroute To/From Lovelace
c. Participant Phones During Evenings or Weekends
d. Friend or Relative of Participant Phones Participant While He Is in Albuquerque
e. Emergency Contact

Appendix I - 12 - Hour Urine Specimen Collection Instructions

VI. Logistics and Medical Records Manuals

A. Logistics

1. Schedulers

a. Purpose

(1) The role of the Scheduler is critical to successful conduct of the Veterans' Health Study. The Scheduler is responsible, through the Senior Scheduler (a "working" supervisory position), to the Deputy Project Director for establishing telephone contact with prospective study participants; for motivating them to participate in the medical and psychological examinations, and for making an examination appointment; for answering their questions about study participation; and for initiating their travel arrangements through the on-site Travel Agents.

(2) The Scheduler is further responsible for initiating and maintaining records relative to the scheduling function, and for the accurate and timely input of selected data into the Veterans' Health Study Logistics Data Management System.

b. Qualifications

Schedulers are to be selected from applicants who have demonstrated an ability to relate to others over the telephone in an assertive but positive and pleasant manner. Care should be taken to choose applicants with experience in work requiring telephone call initiation rather than call answering alone. Such experience may commonly be obtained by telephone interviewers, telephone surveyors and telephone collectors. It is required that persons selected for the position of Scheduler possess at least a high school diploma or the equivalent.

c. Training

(1) To ensure the effective performance of their duties, Schedulers are to receive training, orientation or familiarization in a number of specific subject areas such as telephone etiquette and refusal conversion.

(2) In addition, many of the training topics listed in the "Participant Advocates" Section following are also required training for Schedulers.

d. Protocols

(1) Throughout the conduct of the Veterans' Health Study, the names, addresses and phone numbers of eligible, prospective study participants will be provided by the Centers for Disease Control and will be transmitted on a regular basis to the Lovelace Veterans' Health Study Data Management System. Receipt of this data triggers the mailing of an introductory information packet to each prospective participant. Included in the packet is a letter from the Veterans' Health Study Medical Director inviting the prospective participant to call Lovelace Medical Foundation, toll free, and arrange for an examination appointment or, to return a stamped, self-addressed "interest card" indicating his interest and advising Lovelace of the most convenient time to call him. The prospective participant is further advised in the letter that if he does not wish to call at this time, a Lovelace staff member (Scheduler) will phone him in several weeks.

(2) Each week, the Data Management System will assign names, addresses and phone numbers of prospective veteran participants to the Schedulers based on the veterans' postal zip codes. Each Scheduler then becomes responsible for contacting the prospective participants who reside in one of four areas of the country, i.e., the Northeast, Southeast, Midwest and Far West. Calls to veterans who reside outside of the continental United States are assigned to Schedulers on an individual basis.

(3) If ten to fourteen (10-14) days pass with no response by the prospective participant, the assigned Scheduler will call the prospective veteran participant and introduce himself/herself as a representative of Lovelace Medical Foundation in Albuquerque, New Mexico. The Scheduler will first answer questions the veteran may have regarding the study and will then ask the veteran to make an examination appointment. The Scheduler will honor a veteran's request for more time and/or information before committing to an appointment and will establish a convenient time and date for a return call.

(4) Any veteran refusing to participate will be evaluated as to whether or not he should be reapproached through a refusal conversion procedure. The names of veterans whose refusals are unable to be converted, and the reasons for refusal, will be documented and reported to the Centers for Disease Control.

(5) Once a veteran has been scheduled for an examination appointment, he is immediately put in touch with, or contacted by, one of the on-site Travel Agents who handles

his travel arrangements. Prospective participants who have been scheduled for an examination appointment and booked for travel are assigned in blocks of up to twenty-five (25) to a Participant Advocate. The Advocate then becomes responsible for making phone contacts with the participant prior to his departure for Lovelace, coordinating his travel to/from Albuquerque, and for facilitating his progress through the various examination stages.

e. Procedures

(1) Names, addresses and phone numbers of prospective veteran participants are assigned to Schedulers by means of Scheduler Work Reports, on which phone contacts with the veteran are documented.

(2) The initial mailing, including the letter of invitation from the Veterans' Health Study Medical Director and the stamped, self-addressed "interest card," is sent to each named prospective participant:

(3) The veteran receives his study invitation and phones Lovelace by calling the "800, toll-free" number provided.

(4) This contact is documented on a Veteran Call-In Sheet and is later transferred to the veteran's Scheduler Work Report. A veteran who phones in himself is reassigned to the Scheduler taking his call.

(5) The veteran receives his study invitation and returns the addressed, stamped interest card provided.

(6) His assigned Scheduler calls him.

(7) If ten to fourteen (10-14) days pass with no response from the veteran, his assigned Scheduler calls him.

(8) When telephone contact is established between the Scheduler and the veteran, the Scheduler introduces himself/herself, describes the purpose of the phone call and asks the veteran to make an examination appointment, resulting in one of the following:

(a) The veteran agrees on an appointment date and the Scheduler transfers him to, or arranges for him to be contacted by, an on-site Travel Agent who makes his travel arrangements. Documentation of travel arrangements is made on a Travel & Mail Prompt Form by either the Scheduler or the on-site Travel Agent. Veterans scheduled for examinations and booked for travel are sent a second mailing containing detailed information about their study participation.

(b) The veteran requires additional information or motivation before agreeing to an appointment. The Scheduler will provide detailed information, as necessary, about the examinations to be performed; may remind the veteran that his family or guests (up to three additional persons) may stay in his hotel room at no charge and that they will be assisted with sightseeing, etc. during their visit; may emphasize the importance of the veteran's participation to the study; may emphasize interesting aspects of Albuquerque, New Mexico or the Southwest; may remind the veteran of the $300.00 bonus for completing the examinations, or may mention other positive motivating factors.

(9) If the veteran agrees to an appointment, he is handled as above.

(10) The veteran requires additional time before committing to an appointment date: The Scheduler arranges to make return calls at times convenient to the veteran, until he either agrees or refuses to make an appointment. Return calls are managed and prompted by establishing a time and date for recalling the veteran on the Scheduler Work Report and filing it in a "tickler file" under the appropriate date. At the beginning of each work day, the Senior Scheduler is responsible for reviewing the "tickler file" and reassigning the day's return calls to the appropriate Schedulers.

(11) The veteran requires our assistance in obtaining permission from his employer to be absent from work during his study participation: The veteran will be mailed a special letter which HE, AND ONLY HE may give to his employer. The letter will explain the importance of the study and of the veteran's participation. The letter will invite the employer to call the Lovelace Veterans' Health Study management or, if necessary, the CDC in Atlanta to authenticate the study. Any employer who so contacts any member of the Veterans' Health Study staff may be advised of the nature and authenticity of the study. However, the employer MAY NOT BE TOLD THAT HIS EMPLOYEE HAS BEEN INVITED TO PARTICIPATE. The authenticity of the letter given to the employer may be verified as long as the name of the employee and any reference to his possible participation ARE NOT MENTIONED.

(12) The veteran refuses to make an examination appointment: His case is evaluated by the Senior Scheduler and the Deputy Project Director, and a decision is made as to whether or not he should be reapproached through a refusal conversion procedure. If so, the veteran is sent a special

letter explaining in detail the importance of his participation in the study, thanking him for his participation and cooperation thus far, and inviting him to phone Lovelace toll-free should he wish additional information or to schedule an appointment at a later date. This letter will contain a toll-free number to call. Two to three months later, a final follow-up call is made by a Scheduler who did not have the initial contact with the prospective participant. Should the veteran continue to refuse an appointment, no more effort will be made to persuade him as this might be interpreted as harassment.

(13) The veteran agrees to an appointment, later cancels and refuses to reschedule it: This situation will be handled in a manner similar to that of the veteran who refuses to make an appointment (see above).

(14) If telephone contact cannot be made with the veteran, it is because of one of the following:

(a) There is either a busy signal or no answer at the veteran's listed number.

(b) The call will be repeated until contact is made.

(c) The number called is verified to be incorrect.

(d) Other numbers provided are called until contact is made; an inquiry is made to Directory Assistance for a correct number.

(15) If a correct number is provided by Directory Assistance, it is called until contact is made.

(16) If a correct number is not available, a request is made of Directory Assistance to verify the veteran's address. If the veteran's address is verified to be correct, another mailing is sent to him including a request to contact the study Logistics Office.

(17) If his address is incorrect, tracing procedures are begun to locate him.

(a) The veteran is reported to have no phone.

(i) The task of physically locating him and asking him to go to a phone and call the Veterans' Health Study at Lovelace will be performed by Equifax, Inc., a professional tracing agency. Equifax,

Inc. is currently under contract with the Centers for Disease Control to locate these same veterans for a phone interview before they are contacted by Lovelace. As a result, they will know the location of most phone-less veterans and they are committed with respect to the Assurance of Confidentiality requirement.

(ii) A friend or relative of the veteran is contacted and asked for the veteran's number or requested to have the veteran contact the study office.

NOTE: During contact with a friend or relative of the veteran, ABSOLUTELY NO REFERENCE IS TO BE MADE TO THE VETERANS' HEALTH STUDY OR TO THE VETERAN'S POSSIBLE STUDY PARTICIPATION! There is no exception to this rule, even if the person contacted claims to know about the study. They should be informed that because of the strict requirement to protect the confidentiality of each veteran whom we contact, we may discuss our business only with the subject veteran himself. No reference should be made to the veteran's recent telephone interview for the VETERANS' HEALTH SURVEY. If the veteran's number is obtained, it is called until he is contacted.

f. Scheduling Control

Among the situations which may result from the participant scheduling operation are several which must be prevented. These include scheduling more veterans than may be effectively processed [i.e., more than twenty-five (25)] in any given block date, and erroneously reporting a block date to be fully scheduled, consequently failing to fill that date. To avoid these and other troublesome problems the following controls have been established:

(1) The Master Schedule Board:

(a) Covers practically an entire wall in the Scheduling Center, is easily monitored by each Scheduler and is structured in the form of a very large, four (4) month, block calendar. The Senior Scheduler is responsible for monitoring the scheduling activity of the Schedulers and for accurately recording in the appropriate master schedule block, the number of veterans scheduled for that particular date. The number is updated as necessary to reflect scheduling changes on a real-time basis ("as they occur").

(b) As soon as twenty (20) veterans have been scheduled in any block date, the Senior Scheduler is responsible for

assigning the completion of scheduling for that date to a single Scheduler, thus preventing overscheduling on that date.

(c) While Schedulers always attempt to schedule appointments on dates most convenient to veterans, they also always encourage veterans to schedule on those dates closest to being full. At the end of each working day, the Senior Scheduler supervises the reconciliation of number of scheduled veterans, as indicated on the master board, with the actual names of veterans recorded as scheduled on the respective Scheduler Work Reports (filed by block date). This process ensures that the master scheduling board accurately reflects scheduling activity.

(2) The Scheduler Work Report:

Generated by the Veterans' Health Study Data Management System for each prospective participant and is physically maintained in the Scheduling Center AT ALL TIMES until the veteran has completed his examination, has refused scheduling with no hope of conversion, or has been classified as impossible to contact. This procedure lessens the possibility of a Work Report being misplaced or destroyed.

(3) The Data Management System:

Supports the Scheduling function by accepting input of data resulting from each Scheduler's activity, and maintaining by block date an ongoing record of scheduling progress which may be compared and reconciled with information recorded on the master board and/or active Scheduler Work Records. In addition, the Data Management System generates, on a regular basis, a broad spectrum of reports further ensuring accuracy and promptness in Logistics activity. (Refer to the Lovelace Veterans' Health Study Data Management Manual, Logistics Section).

g. Security and Confidentiality

The security of Scheduling operations, as well as the confidentiality of resultant participant data, is assured by the following safeguards:

(1) All employees involved in the scheduling operation have been briefed on the requirement for assuring the confidentiality of veteran identification data and, have indicated in writing, acknowledgment of the penalty for violation of this requirement.

(2) All veteran data resulting from the scheduling function are stored either on "hard copy" records or in the study electronic data management system. All "hard copy" records are kept secure under lock and key except when actually in use, and are destroyed by shredding or incineration when no longer needed. Access to participant information in the electronic data management system requires specific access codes and procedures available only to study Logistics staff members.

h. Equipment and Supplies

The following are used by the Scheduling staff in the performance of their function:

(1) IBM XT Personal Computer with Epson dot matrix printer, programmed with "VISTA-FORM" to provide for up-loading of telephone call activity data to the study data management system.

(2) Push-button telephone complete with headset and WATS line.

(3) Wall size calendar "Master Scheduling Board" on which single and blocks of scheduled veterans are recorded.

(4) Forms mentioned above including:

(a) The Scheduler Work Report.

(b) The Veteran Call-In Sheet.

(c) The Travel & Mail Prompt Form.

i. Quality Control

The level and quality of work performed by the Senior Scheduler and the Schedulers will be monitored and controlled by the Deputy Project Director based on:

(1) Personal observation and supervision:

(a) Of the Senior Scheduler by the Deputy Project Director.

(b) Of the Schedulers by the Deputy Project Director.

(c) Of the Schedulers by the Senior Scheduler.

(2) Productivity reporting from the Veterans' Health Study Data Management System.

(3) Reports and feedback provided by the Senior Scheduler concerning Scheduler performance with regard to:

(a) Percentage of appointments scheduled on initial participant contact.

(b) Percentage of appointments scheduled relative to number of participants contacted.

(c) Percentage of participant contacts resulting in refusal.

(d) Percentage of refusals converted.

(4) Data obtained from completed Participant Satisfaction Questionnaires.

2. Participant Advocates

a. Purpose

Each block of study participants will be matched with a specific Participant Advocate whose function will contribute greatly to the overall success of the medical examination portion of this study. Each Participant Advocate is responsible to the Deputy Project Manager for orienting assigned study participants to what they may expect during their stay at Lovelace and in Albuquerque; for coordinating participants' lodging, their study-related transportation, their collection of required urine specimens, and their appearance for examination appointments; for scheduling and coordination of their results interviews, payment of their examination completion bonuses and coordination/facilitation of their departures. In addition, the Participant Advocate will serve as a counselor and advisor to each participant to better ensure that their study participation is a positive experience.

b. Qualifications

Participant Advocates are to be selected from applicants who have demonstrated an ability to relate effectively and positively to individuals of various backgrounds and cultures. While not a strict job requirement, it is desirable that Participant Advocates possess a bachelor's degree or equivalent and experience in counseling or a "helping" profession.

c. Training

To ensure the effective performance of their roles, Participant Advocates are to receive training, orientation and familiarization in a number of relevant subject areas.

(1) Lovelace Medical Center; its history, physical layout, organizational structure and current operation. This is accomplished by attendance at the Lovelace New Employee Orientation Session.

(2) The Veterans' Health Study; its structure, organization and objectives. Conveying this information is the responsibility of the Project Director or Deputy Director.

(3) The physical layout of study examination areas.

(4) The layout and operation of the lodging facility, including becoming familiar with the hotel manager and other key hotel staff.

(5) The layout of the Albuquerque International Airport

(6) The probable psychological status of the study participants. Study psychologists or psychology consultants will present briefings on pertinent topics to the Advocates and will be available to discuss concerns Advocates may have as they work with the participants.

(7) Study examination equipment and procedures. Whenever possible, advocates will have participated in the exams as a "participant." The Clinic Staff will also be available to provide information or answer specific questions.

(8) Emergency procedures including the basic techniques of cardiopulmonary resuscitation. For anyone not already certified, Lovelace Medical Center provides CPR certification programs at no cost to employees.

(9) Techniques for dealing with "problem" individuals and difficult interpersonal situations. Dr. Pamela Palmer will present a seminar on oral confrontation techniques.

(10) Interesting aspects of Lovelace Medical Center, the City of Albuquerque, the State of New Mexico and the Southwest. This information is provided by the Albuquerque Visitors and Convention Bureau.

(11) Data management procedures (keeping track of and handling paperwork).

(12) Procedures and protocols for serving and relating to study participants (as detailed in this Procedure manual).

d. Procedures Relative to Day of Participation

Procedures and protocols to be followed by Participant Advocates are specified relative to the day of participation (i.e., Arrival Day, Medical Examination Day, Psychological Examination Day and Day of Departure).

(1) Prior to Participant Arrival Day

(a) Approximately one week before departing for Albuquerque, each scheduled participant will be mailed a packet of information including a photograph of the Participant Advocates. This provides for a more personal or human connection with the participant. Then, several days prior to the participant's scheduled departure for Albuquerque, the Participant Advocate will contact the participant by phone. During this contact, the Advocate will introduce himself/herself, verify the participant's scheduled appointment and travel arrangements, answer any questions the participant may have and deal with any last minute problems the participant may be experiencing concerning his planned visit to Lovelace. The Advocate is reminded of the numerous subjects to be addressed during this contact by means of the Pre-Arrival Telephone Call sheet.

(b) The Participant Advocate will also confirm special scheduling arrangements for any participant who plans to arrive in Albuquerque prior to his "block date" or who intends to remain in Albuquerque later than the day of the results interview. Participants may arrive prior to their "block date" or remain later than their results interview day for one or a combination of two reasons:

(i) Particular problems scheduling their travel by the study Travel Agents, in which case the extra charges are paid by Lovelace.

(ii) Desires of the participant to visit in which case the extra charges are the responsibility of the participant.

(c) The Participant Advocate will document all phone contact attempts with participants by making notations on the appropriate Participant Advocate Report form. Participant Advocate Report forms representing participants who require additional phone contact will be filed in an active status and monitored daily to ensure that necessary follow-up contacts are attempted.

(d) The Participant Advocate will provide the study lodging facility with a final guaranteed number of participants five (5) days prior to the arrival of the participants. Should any participant cancel plans to participate during the five (5) days prior to the scheduled arrival, the Participant Advocate will report the cancellation to the lodging facility NO LATER THAN FORTY EIGHT (48) HOURS prior to the participant's original scheduled time of arrival.

(e) The Participant Advocate will, at least 24 hours prior to the arrival of each scheduled participant, furnish the lodging facility with the following:

(i) Name and assigned study identification number of each arriving participant.

(ii) Arrival and departure dates for each participant, to include specific instructions concerning any charges which are to be the responsibility of the participant.

(iii) Instructions concerning the issuance of special meal coupons to early arriving or late staying participants.

(iv) Participant arrival and departure times for the use of the lodging facility in scheduling their courtesy transportation for participants to/from the airport, train station, or bus station.

(v) Directions for providing participants with "wake-up calls" on their medical and psychological examination days.

(vi) Special messages to be given to participants when they register for their rooms, including the "Important Numbers" and "Message - Come to see me" cards.

(f) Prior to the arrival of participants, the Participant Advocate is responsible for ensuring that a "hospital-type" identification bracelet is prepared for each arriving participant.

(2) Participant Arrival Day

On Participant Arrival Day, the participant advocate will:

(a) Report to the participant lodging facility (hotel) by 12:00 noon and contact the appropriate airlines to confirm flight arrival times.

(b) Monitor the arrival of study participants through the hotel front desk clerks and courtesy van drivers. During prearrival phone contacts with participants, the Participant Advocates have provided instructions on how to request courtesy transportation to the hotel by phoning from the Albuquerque International Airport, train station, or bus station.

(c) Meet arriving study participants individually; attach to the wrist of each participant a "hospital-type" identification bracelet preprinted with name, date of birth, participant identification number and block position (sequence) number (1-25); inform each participant when and where to report for study orientation. The Participant Advocate will, at this time, ensure that he/she has recorded each participant's hotel room number and will collect travel expense receipts from those participants who have them. The Participant Advocate will also ensure that each arriving participant has signed required medical release authorization and medical consent forms and issue to each arriving participant a gym suit to be worn on the participant's medical examination day and a name tag (first name only) to be worn throughout participation in the study.

(d) Report as scheduled for participant orientation and conduct orientation based upon the sample outline.

(e) Issue to each participant, one ice chest containing a 1.5 liter urine collection container and two (2) frozen ice packs; provide participants with instructions, (given in Appendix I), both orally and written, on how to collect urine specimens over a twelve (12) hour period; provide each participant with a laboratory questionnaire form and instructions for its completion and submission to the lab personnel.

(f) Advise participants of various special activities which have been arranged for their entertainment and provide each participant with a handout sheet describing these activities. An informed person will be made available at the hotel to provide study participants and their families or guests with information on and assistance with recreational activities in Albuquerque and surrounding areas.

(g) After conducting participant orientation, check with the hotel registration desk and/or commercial carriers concerning the status of participant(s), if any, who failed to report to orientation.

(h) Prior to leaving the lodging facility, ensure that a study information sheet (containing all necessary information as provided during study orientation) is left for any participant who is expected but has not yet arrived.

(i) Remain "on-call" until the assigned participants have completed the medical exam portion of the study.

(3) Participant Medical Examination Day

On the day that his/her assigned participants are scheduled for medical examination, the Participant Advocate will:

(a) Report to the participant lodging facility by 6:30 a.m. Prior to leaving home for the lodging facility, the Advocate will telephone the lodging facility to ensure that wake-up calls will be made to participants between 6:00 a.m. and 6:15 a.m.

(b) Confirm that the Lovelace van or contract bus has arrived at the lodging facility no later than 7:00 a.m.

(c) Greet participants as they enter the lodging facility lobby. Ensure that each participant who attended orientation the previous evening has his urine collection equipment. (Participants who arrived too late for orientation will collect their urine specimen during the evening/night following their medical examination.) Collect travel vouchers and supporting receipts from participants who wish to claim incoming travel expenses.

(d) Coordinate boarding of the Lovelace van or contract bus by study participants so that departure for the study clinic can occur no later than 7:15 a.m. Ensure that each participant carries his urine specimen collection equipment with him onto the van or bus.

(e) Telephone the study clinic, confirming departure of the van to the Clinic Nurse. Inform the Clinic Manager of any participants who failed to arrive and any participants who did arrive but were unexpected.

(f) As soon as possible, leave the lodging facility and report to the Clinic Manager at Lovelace Medical Center. Should the Participant Advocate experience a situation or problem which prevents him/her from reporting to the Clinic Nurse by 9:00 a.m., he/she is to contact the Office Advocate to request back-up.

(g) Assist the Clinic Nurse as needed to facilitate the progress of participants through their examination stations and to ensure that they promptly meet their exam schedules.

(h) Meet study participants as they complete their medical examinations, inform them of the next day's schedule, and that the NO ALCOHOL RESTRICTION IS STILL IN FORCE!

(i) Coordinate the departure of medically examined participants by Lovelace van to the hotel.

(4) Participant Psychological Testing Day

On the day his/her assigned participants are scheduled for psychological testing, the Participant Advocate will:

(a) Report to the hotel and assist the staff Psychologists as needed in coordinating the participant examination process.

(b) Coordinate the process by which participants initially sign for their traveler's checks. Traveler's checks are brought to the hotel by AAA agents on Psychological Examination Day for signatures. They are then given to the Advocate for safekeeping until they are issued to the participant following the completion of the debriefing phase.

(c) Obtain from the Medical Records Clerk, a list of the Advocate's currently assigned participants to include the names of the physicians who performed their physical examinations. Based on the participants' departure schedules and the identity of their examining physicians, prepare a master schedule and appointment chart for the results interviews; prepare individual participant results interview appointment cards.

(d) As assigned participants complete their psychological tests, the Participant Advocate will:

(i) Ensure that each participant receives the cash allowance for his evening meal and entertainment, and reimbursement for any allowable travel expense receipts submitted.

(ii) Remind each participant that the alcohol restriction is no longer in force.

(iii) Inform each participant of his results interview appointment.

(5) Participant Results Interview Day

To facilitate the debriefing process and prepare for departure of the participant, the Participant Advocate will:

(a) Obtain the participants' examination records as made available by the Medical Records Clerk, traveler's checks and return airline or train tickets and report with them to the lodging facility.

(b) Provide study examination records for the use of appropriate interviewing Physicians and Psychologists; assist Results Interviewers by facilitating the flow of participants.

(c) Ensure smooth and efficient flow of participants and their respective medical records; distribute medical records to Results Interviewers as appropriate; collect medical records from Results Interviewers and check to ensure that each record has been addressed by both an interviewing Physician and Psychologist before it is classified as complete; maintain completed records in the case provided.

(d) Collect and review Participant Satisfaction Questionnaire.

(e) Confirm participant's return travel arrangements: Confirm flight and train schedules, etc.; ensure that each departing participant has and is aware of the "800 Travel Assistance" number to use if needed, and ensure that each departing participant knows how, when and where to obtain the lodging facility courtesy transportation back to the airport, train station, or bus station.

(f) Disburse stipend (traveler's checks), obtaining receipt.

(g) Issue participant's return flight or train ticket.

(h) Have participant sign medical records release consent form, giving participant a copy.

(i) Confirm arrangements for participants who are being held over at project convenience.

(j) Provide participant with forms and instruction for requesting return home expense reimbursement.

(k) "Read" participant's hypersensitivity test and record results on the appropriate form in the medical record.

(l) Answer final questions from participants, provide information as requested, express appreciation for participation in the project.

(m) Promptly return to the Veterans' Health Study office, the completed medical records, Participant Satisfaction Questionnaires and bonus disbursement receipts.

e. Quality Control

(1) The level and quality of the performance of the Participant Advocates' job responsibilities will be monitored and controlled by the Deputy Project Manager based on personal observation and supervision, and data obtained from the Participant Satisfaction Questionnaire.

(2) Quality control of hypersensitivity test reading is the responsibility of the Special Assistant for Quality Control and Scientific Affairs, and will be monitored by means of blind repeat readings as described in the "Hypersensitivity Testing" Procedure Manual.

f. Security and Confidentiality

The security of Participant Advocate activities, as well as the confidentiality of resultant participant data is assured by the following safeguards:

(1) Each and every employee involved in the advocate operation has been briefed concerning the requirement for assuring the confidentiality of veteran identification data and has indicated in writing, his/her acknowledgment of the penalty for violation of this requirement.

(2) All veteran data resulting from the advocate function are stored either on "hard copy" records or in the study electronic data management system. All "hard copy" records are kept secure under lock and key except when actually in use, and are destroyed by shredding or incineration when no longer needed. Access to participant information in the electronic data management system requires specific access codes and procedures available only to study Logistics staff members.

3. Travel Agents

a. Purpose

Travel arrangements are a critical factor in the successful completion of this study. For those participants who do not travel frequently, a change in environment and dealing with unknown factors can be quite stressful. During its conduct of

the Veterans' Health Study, the Lovelace Medical Foundation intends to provide full, efficient, convenient but cost-conscious round trip travel services to all study participants. To meet this objective, Lovelace has contracted with the AAA Travel Service to handle air, rail, bus and automobile travel arrangements for Veterans' Health Study participants.

b. Supervision

Under this contract, the AAA Travel Service provides, at the Lovelace site, the services of three full-time, fully trained, senior travel agents equipped with AAA airline reservation terminals. While general supervision of the on-site travel agents is performed by AAA management personnel, their direction with respect to Veterans' Health Study operations is conducted by the Assistant Project Manager.

c. Procedures

The purpose of the following procedures is to provide prompt, convenient and efficient travel arrangements for each participant while ensuring the most economical travel costs to the U.S. government. When a participant has committed to a Logistics Scheduler for an examination date, his travel arrangements are initiated, completed and controlled through the following steps:

(1) The Scheduler requests travel arrangements for the participant by intiating and submitting a Travel & Mail Prompt form to the Travel Agent. Prior to contacting the participant, the Travel Agent prepares optimum reservations for air travel to/from Albuquerque. When acceptable travel plans are arranged, they are documented and reported by the Travel Agent who completes and returns the Travel & Mail Prompt form to the Scheduler.

(2) If the Travel Agent is unable to complete acceptable travel arrangements with the participant during their initial phone contact, the Travel Agent will conduct return calls as necessary to complete arrangements. Return calls are prompted and managed by a daily "tickler file" maintained by each Travel Agent for incomplete Travel & Mail Prompt forms.

(3) The number of participants booked to arrive in Albuquerque is controlled by a card file mutually maintained by the Travel Agents. This file is arranged by dates of arrival. As travel arrangements are completed, a card containing name, mode of travel and arrival date/time is filed by the

appropriate arrival date. Each card also indicates the "block date" so that at a glance one may see how many participants are booked to arrive on any date and of those, how many are arriving one or more days before their regular "block date" (day of study orientation).

(4) Special information concerning which participants are arriving early, staying late, accompanied by guests, etc., is reported through the Schedulers to the Participant Advocates by comments made by the Travel Agents on the Travel & Mail Prompt forms.

(5) To conform to Study schedules and provide for optimum participant comfort, the Travel Agents will book incoming and departing participants as follows:

(a) When booking participants to travel by air, the Travel Agents will attempt to make reservations and connections as convenient for the participant as possible, to be booked for "on-line" (same carrier) connections and on flight routes with the minimum number of connections.

(b) Every attempt will be made to bring each participant to Albuquerque by 2:00 p.m. on the day before his medical examination. Any participant who cannot be scheduled to arrive by 4:00 p.m. on that day may, with written approval of the Deputy Project Director, be scheduled to arrive one (1) day earlier (an "early-bird").

(c) Participants who cannot be booked to depart Albuquerque by 6:00 p.m. on the day of their results interview may, with written approval from the Deputy Project Director, be scheduled to depart one (1) day later (a "holdover").

(6) To help ensure a convenient and pleasant travel experience for each participant, the on-site Travel Agents will provide special services as follows:

(a) Arrangements to meet the needs of handicapped participants and participants having other requirements such as special in-flight meal, etc.

(b) Assistance to participants who wish to bring guests or to incorporate personal travel with their air flight to/from Albuquerque.

(c) Assistance to participants who choose to travel by rail, bus or private automobile.

(d) Delivery by certified mail of the participant's airline or train tickets. Tickets are initiated by the on-site Travel Agent, generated at the Albuquerque AAA Travel Service office and sent to participants with personal luggage tags, the AAA toll-free "800 Travel Assistance" phone number, airline boarding passes when available and maps with instructions to provide easy progress in connecting airports. Bus travel reservations may be booked by the Travel Agents. However, tickets for bus travel must be purchased by the participant at the point of departure and reimbursed later.

(7) Participant travel expenses to the study will be managed and contained through application of the following criteria:

(a) Travel Agents will book participants on airline flights with the lowest available fares except when the lowest fare arrangements create a hardship for the participant because of time or distance from his/her home or because of an unacceptable number of necessary flight connections. Before booking fares higher than the lowest available, Travel Agents must obtain written approval from the Deputy Project Manager. If higher fares are booked without the required approval and a lower fare is found to have existed, AAA will be compensated only for the lower fare.

(b) Participants choosing not to travel by air will be reimbursed only for that portion of their travel expenses not exceeding the lowest roundtrip air fare plus incidental expenses which could have been arranged for their trip.

(8) When a Travel Agent assists a participant by booking reservations for relatives or guests, payment for these reservations will be handled by one of the following methods:

(a) The participant provides a current credit card number to the Travel Agent. While the participant is in Albuquerque, the Participant Advocate will see that the participant has an opportunity to sign for the charged reservations.

(b) The Travel agent will "release" the guest reservations to the airline so that the participant can pay for them through his local travel agency.

(9) When a participant is assisted by having personal air travel booked in conjunction with the round trip to/from Albuquerque, the Travel Agent will ensure that the study is charged no more than the lowest air fare by the most direct route between Albuquerque and the participant's home.

(10) Should a scheduled participant choose not to participate in the study after receiving an airline or train ticket, he will be instructed to mail the ticket back to Lovelace. Each ticket can only be refunded to the AAA Travel Service and cannot be exchanged for another ticket to/from a destination other than Albuquerque. If the participant fails to return the ticket, it will be classified as lost. AAA may be reimbursed by Lovelace for lost airline tickets or charges for prepaid airline tickets to be picked up at an airport when necessary, and for nonrecoverable tickets whose loss could not have been reasonably prevented by AAA.

d. Security and Confidentiality

Security and confidentiality of data related to the planning and arrangement of participant travel are accomplished by the following:

(1) Each on-site Travel Agent and all other AAA employees having access to knowledge of the participation of any study member will have been briefed concerning the study assurance of confidentiality and will have signed the appropriate form of acknowledgment.

(2) All travel planning paperwork containing the name of any participant will be secured under lock and key when not in actual use and will be destroyed when no longer needed or transferred to CDC, as required.

(3) AAA Travel Service will purge any and all of its records of any participant names such that at the end of the study there will be no traceable record through AAA or any common carrier records of any study member's participation.

e. Equipment and Supplies

All necessary equipment and supplies will be provided by the AAA Travel Service under the terms of the contract.

f. Quality Control

(1) As stipulated in the contract, AAA is to monitor all participant complaints and problems and bring each to the attention of the Deputy Project Manager.

(2) The quality of the work performed by the AAA Travel Service and its representatives will be monitored and controlled by the following methods:

(a) Direct observation by the Deputy Project Manager to include periodic independent comparison of airline fares.