T3 MANUAL OF OPERATIONS - VOLUME II

TABLE OF CONTENTS

TABLE OF CONTENTS (Continued)

CHAPTER PAGE

1 STUDY FORMS

STUDY FORMS - INSTRUCTIONS AND DEFINITIONS (Continued)

TABLE OF CONTENTS (Continued)

CHAPTER 1

STUDY FORMS

1.1 FORMS FOR DATA COLLECTION

Each of the forms used for data collection is discussed in this section. There are several parts to the description of each form.

A. Overall description of the form, including the purpose, person responsible for its completion, the source of the information, the time frame for form completion, and any general instructions for timely and accurate form completion.

B. A description of the individual items on the form, including definition of clinical terms and a discussion of how each item should be completed.

C. A copy of the form.

1.2 GENERAL INSTRUCTIONS FOR COMPLETING STUDY FORMS

1.2.1 Completing, Reviewing, and Labeling Study Forms

Black ink should be used for completing the forms. For items which cannot be answered by a check mark (/) or an "X," print clearly all responses in the space provided. Do not use abbreviations unless necessary and then use only widely recognized abbreviations. A copy of each completed form should be retained for Clinical Center files.

The first items to be completed on any patient data form are the Clinical Center and specific hospital number, ID number, and form type. The form type consists of two preprinted letters and either a preprinted 01 (for a form only completed once) or a sequence number (for a form which may be completed more than once). The sequence number is the serial count for each patient of a specific form type submitted to the Data Coordinating Center. The form types to be entered on Form 12, Missed Follow-up Form, Form 13, Follow-up Contact, and Form 63, One-Year and Two-Year Follow-up Contact Form are exceptions to this rule. The form type for Forms 12, 13 and 63 should

refer to the contact for which the form is completed. For example, a Form 13 completed in connection with the six-week follow-up should have a form type of FU01. A Form 13 or 63 completed in connection with the one-year follow-up should have a form type of FU02. A Form 63 completed in connection with the two-year follow-up should have a form type of FU03.

The Patient Inventory List (T3 Forms 54A and 54B) is designed for the Coordinator's convenience in keeping count of these forms. Each additional form of a specific type is assigned the next available sequence number. Next the NAME CODE and the date of the examination or event are completed. The ID number and sequence number, if space is provided, are recorded in the lower right-hand corner of each page of the form. The forms are to be completed by the Research Coordinator or other T3-certified staff members and checked by the Research Coordinator before shipment.

The policy of the Data Coordinating Center is to process the information as submitted without interpretation or second guessing what the recorder had intended. The Clinical Center staff are requested to complete the forms as clearly and as legibly as possible and to follow the conventions described below (Sections 1.3 - 1.7) in reporting certain data to minimize the possibility of errors in processing the data collection forms.

Data Entry guidelines followed by the Data Coordinating Center data entry staff are given in Chapter 2 of Volume II of the Manual of Operations, Exhibit 2-2. These guidelines clarify the implications of the conventions mentioned above.

When a form is returned to the Research Coordinator at the end of the examination or procedure, it should be reviewed promptly, preferably while the patient is still in the Clinical Center, to assure that all required information is complete and has been recorded in a legible, unambiguous fashion. Any administrative information re-

quested at the end of the form is supplied by the Research Coordinator.

1.3 RESPONSES ANSWERED BY A CHECK MARK (/) OR "X"

If a response is to be answered by a check mark (/) or an "X," then only a check mark or an "X" within the parentheses is the acceptable response.

1.4 NUMERIC RESPONSES

When a numeric response is requested, the entire response space is to be completed. Leading zeros should be used, if necessary. For example, heart rate has three spaces and if a patient's resting heart rate is 87, then "0 8 7" should be recorded in the space.

1.5 LEGIBILITY

If a response is to be answered by other than a check mark or an "X," then the response is to be printed clearly in the spaces provided. Abbreviations are not to be used by the Clinical Center staff unless absolutely necessary and then only widely recognized abbreviations should be used.

1.6 OVERWRITTEN RESPONSES

If the response has been overwritten to carefully delineate the existing mark, the response is acceptable. The tracing of the existing marks should be done in black ink.

If the response has been overwritten to change the response, then the response will be considered illegible unless **THE DESIRED RESPONSE IS CLEARLY CIRCLED AND INITIALED** by the individual making the correction. The incorrect response is to be crossed out. An incorrect numeric or alphabetic response should be completely crossed out, and the correct numeric or alphabetic response written clearly above or below the original response. The correct response should be clearly circled and initialed by the individual making the correction.

Incorrect responses should not be circled, initialed, or indicated by writing "error."

1.7 UNSOLICITED RESPONSES

Unsolicited responses should not be written within the items on the forms. This information cannot be entered into the computer system.

1.8 LABELS

Identification labels for labeling forms are supplied by the Data Coordinating Center. Each Clinical Center is also supplied with labels to be used to identify ECGs, ETTs, angiograms, and Holter recordings. The Research Coordinator is responsible for assuring that the proper labels are used and that all materials for each patient are labeled correctly.