MANUAL OF OPERATIONS

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MODIFICATION OF DIET IN RENAL DISEASE

EKG CENTRAL LABORATORY MANUAL OF OPERATIONS

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The Clinical Center will send one original 8 1/2 by 11 standardized 12 lead EKG recording to the Data Coordinating Center (DCC) plus one copy, as required by the Protocol and Manual of Operations. It will be sent with two copies of the EKG Mailing Form #18.

The Data Coordinating Center will provide the central lab with patient's sex and age. The EKG mailing form will accompany the racing for Identification and Visit Information. The Data Coordinating Center staff will blank out all names and dates on the tracing. Both will be sent to the EKG Lab from the Data Coordinating Center.

The Central Laboratory Technician will complete items 1-10 on the Central EKG Form #35 and then deliver the materials to the two physician interpreters (Figure 1). The interpreters will complete the remaining portion of the form individually and then will review all coded information and reach a consensus. For item #18, Reader 1 will be Dr. Proudfit, Reader 2 will be Dr. Underwood, and a 3 will be the consensus. The latter serves as the "official" interpretation. For each patient, three Form #35's will be returned to the DCC for data entry. Only the consensus form will be reported to the clinical center. In the case of acute concerns, the Data Coordinating Center will phone the involved clinical centers upon notice from the EKG physicians.

Table 1 lists the allowed ranges of interobserver variability for each item on the EKG form. Table 2 details the responsibilities of the Central EKG Laboratory Technician.

Two EKGs from each center will be randomly selected by the DCC to go through this process a second time. In this manner intra observer variability can be analyzed by comparing results from the 1st and 2nd readings of each Central EKG physician.

Figure 1

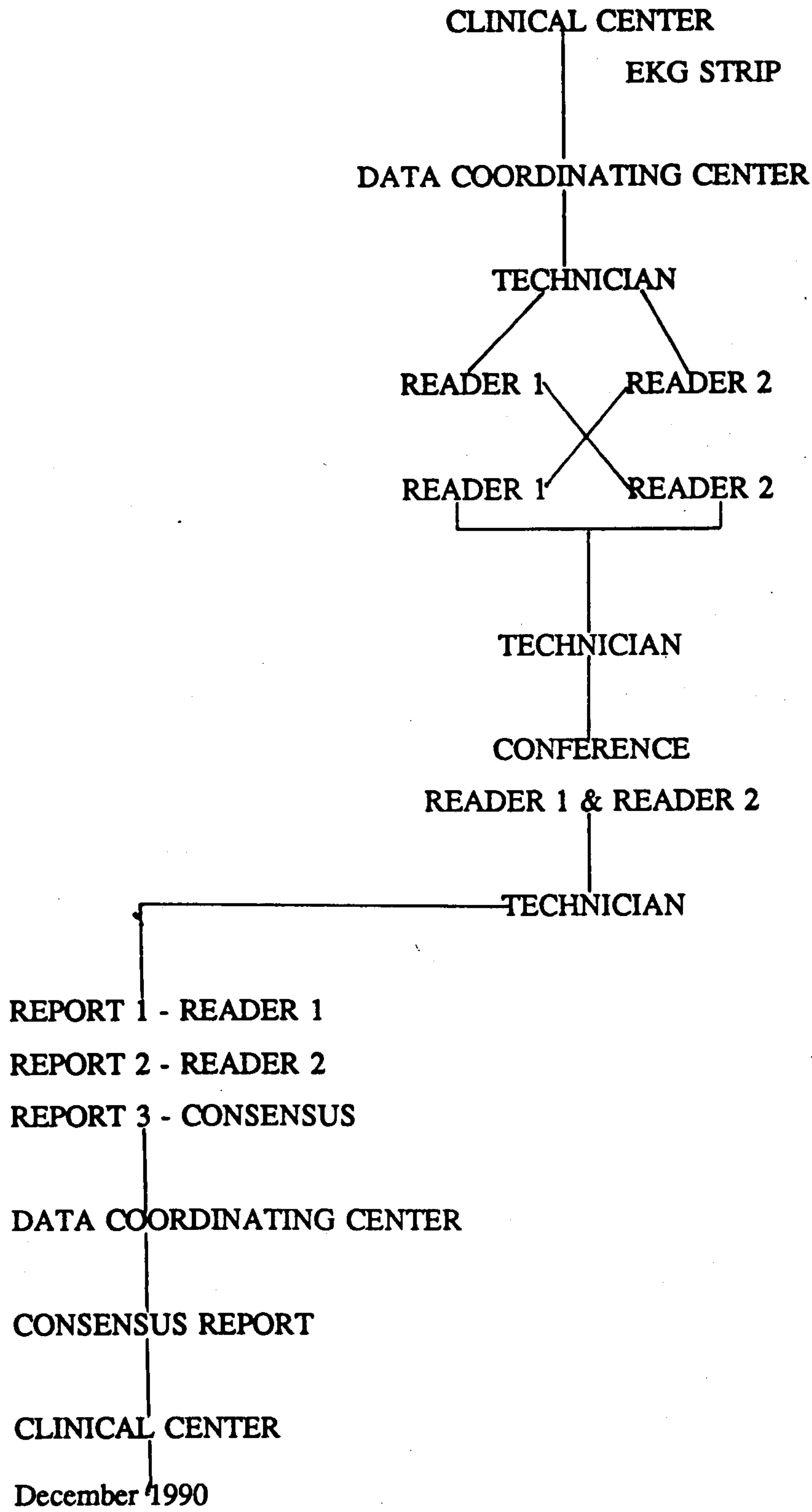

TABLE 1
EKG STANDARDS

Form Item # 6	Heart rate: + or - 5 beats/min. with rate over 100 + or - 10 beats/min. with rate under 100
Form Item # 7	Low voltage: Conformity
Form Item # 8	Lewis index: ± 2
Form Item # 9	Sokolow index: ± 3
Form Item #10	R height in V5 (or V6): ± 2
Form Item #11	QRS angle: ± 15
Conformity	
Form Item #12	Rhythm: Conformity
Form Item #13	QT constant: ± 0.03. If over 0.45 sec. by both interpreters, clinical center will be notified.
Form Item #14	Conduction defect: Conformity
Form Item #15	Myocardial Infarction: Conformity
Form Item #16	Repolarization: Conformity

TABLE 2

Responsibilities of Technician

XEROX EKG mailing form and attach to 3 copies of coding forms.

ROUTINE MEASUREMENTS on coding forms (3).

DISTRIBUTE to physician interpreters (Forms and EKG tracings).

RECEIVE from physician interpreters and distribute to the others.

RECEIVE from physician interpreters.

IDENTIFY differences in interpretation on new code sheets and save for consensus conference (Wit EKG).

RECEIVE from consensus conference.

SEND code sheets (individual and consensus to DCC).