

July 24, 1973

Robert Levy, M.D.  
NIH Building 10 Room 7N220  
Bethesda, Maryland 20014

Dear Dr. Levy:

I fully understand and support your administrative function in questioning and evaluating the feasibility of performing an exercise test at the Third Screening Visit of MRFIT, now scheduled for two centers in late November and for others in early 1974.

I write you wearing many hats but primarily as co-chairman of the MRFIT Clinical Endpoints Committee (CEP) which is largely responsible for MRFIT decisions to undertake:

- 1) the use of computer analysis of ECG's
- 2) to employ the Marquette equipment,
- 3) to perform an exercise test at baseline,
- 4) and to complement this operation with a conventional manual measurement and classification of paper ECG tracings for purposes of comparison, analysis, cross-validation and back-up.

Application of this modern methodology in the current generation of clinical and preventive trials should put NHLI far ahead for subsequent generations. We believe the methodology is ready and that MRFIT is ready to implement it. In this regard I imagine that we have gone through the same soul-searching and cost analyses as did you for the Lipid Research Centers. I prepared a detailed and critical scientific cost analysis of this called: "Revised Memorandum on Exercise Testing in MRFIT" on April 19. Subsequent to that the Steering Committee voted unanimously to proceed as planned.

MRFIT has, of course, been hindered by the inability so far of the NHLI to name an ECG Center. The Clinical Endpoints Committee of MRFIT fully expected this center to be in operation in June. But the Committee has not been defeated by the delays. The CEP Committee has followed the HDFP-ECG experience closely (weekly) and is convinced that its equipment and procedures are feasible for MRFIT. The CEP Committee has prepared the necessary MRFIT protocols and procedures, it has pretested the exercise test and has kept in close touch and direct involvement with the Lipid Research Center's procedures in our local unit and in Birmingham. The CEP Committee has outlined a program for further pretesting and for training of personnel. ~~We have made cost~~

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*blind pc to  
Kuebler  
Zukel  
CEP Committee  
(include  
Ridman)*

*Kiehlberg  
J. Paul  
Steering Committee  
Rambhadraraj  
R. Arinas  
R. Crow  
H. L. T.  
H. Leon.  
W. Latham  
M. Cuddeby*