July 23, 1975

Florence E. Mayer, M.D.
Clinical Cardiac Diseases Branch
Division of Heart and Vascular Disease
National Heart and Lung Institute
National Institute of Health
Bethesda, MD 20014

Dear Florence:

I would like your guidance on the appropriate time and the appropriate mechanism to approach your section with a new or continuing request for the studies on ventricular premature beats now being carried out here. I am of course aware that this will be treated as an entirely new application to enter in full competition with others. I am anxious, however, not to miss the appropriate deadline so that the work may be continuous, if it should be considered noteworthy and supportable by peer review.

We will be solidifying much of the descriptive information in the next month and will have completed by September a cross-over design trial of hygienic measured to reduce cardiac excitability in a small group. Prior to an October 1 grant application deadline there will be inadequate data on which to base any evaluation of whether this work should be continued beyond the 1976 termination date. Around the first of the year, or in the early spring, we should have had enough people through the program to have a pretty good idea where it is going.

I believe that if there is any promise whatsoever in the results thaterms of suppressing ectopic beats, that they should be applied promptly to coronary patients that have excess risk of difficulties from arrhythmias. A reapplication would involvedthe design of a mini-trial along the same lines, to carefully qualtify by repeated induction tests the frequency and typpeof ectopic rhythms followed by a cross-over control trial involving vigorous and systematic intervention on "hygiene," de. stimulants, alcohol, sleep habits and the level of physical conditioning. I would almost be included to attempt this irrespective of the results in the normal groups we are now examining - because of the possibility that ectopic activity in coronary patients might be more affected than "normal" ectopic activity in the healthy population and because of the absence of effective long-term drug therapy. But this is a matter of judgment.

So the problem will be to prepare an application at the appropriate time for continuation of activity, yet at a time when the maximum amount of results are available from current efforts.

I would also like your advice, and that perhaps of Peter, on another matter. We have, since I took over the laboratory in 1972, developed a very competent, skilled and enthusiastic biostatistical and data processing division of our laboratory. You are familiar with the difficulties in getting adequate funding for carrying out important analyses in large volumes of data such as the several population studies available to us

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One of the potential mechanisms for support of this activity would be for us to serve as coordinating center of a small trial. I guess I would simply like to be assured that 1) we are on the early mailing list for RFPs concerning coordinating activities for the trials in the Cardiology Branch, 2) that you and the staff are aware of our interests and skills incconducting such functions, and 3) that you might be able to let me know what needs for such coordinating functions are envisioned in current grant activities that are not yet met, if any.

Our data processing division is headed by David Jacobs, Ph.D., a biostatistician with several years' experience at the Maryland Coronary Drug Project Coordinating Center, and now experience here in coordinating the Prevalence Study and Mortality Review of the Lipid Research Centers, as well as our numerous data processing and analytical responsibilities to MRFIT, HDFP, the Seven Countries Study and our Sudden Death-VPB Study. His section includes 1) a chief programmer who has been with us a number of years and is now a graduate student in computer sciences. 2) A chief data handling supervisor who has been with us for a decade and is highly familiar with record handling of all sorts and a very devoted employee. 3) A data coordinator who has been with us about a decade and is very skilled and setting up forms, protocols and procedures for collaborative studies. 4) An experienced statistician and data editor who has been with the laboratory 20 years and who helps us assure good quality record-keeping.

The staff further consists of another full-time programmer, one and one-half keypunch operators, two clerical persons and student help. The unit is housed in our new comfortable air-conditioned and modern facility in the Health Sciences building with adequate space and communications. From the State legislature, we

have a PDP-12 which is fully operational to conduct most of our programs and amenable to upgrading to conduct more complicated analyses which we now access to the Health Sciences computer center with a Control Data 3300. Our facility also includes two keypunch machines, card sorters and collators, files, two Data Point terminals, one Telex and one Xerox communicator.

This facility and its personnel would, in my opinion, be an ideal coordinating center for a small trial and would be ready to go in terms of decreasing MRFIT activities in early 1976. I simply wanted you to havetthis information.

Cordially yours,

Henry Blackburn, M.D.

HB:cl

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