February 9, 1972

Dr. Adrian Ostfeld
Yale School of Medicine
New Haven, Connecticut

Dear Adrian:

Thanks for letting me review your LRC prevalence study protocol. I hope I am well enough, and decisions are made soon enough, so that I can join your group. At any rate, I am persuing the ECG question with Sheffield, and it is in good shape. We or he, or both, will probably provide a facility for manual processing of conventional paper ECGs, as back-up for the computer procedures.

My comments on the draft are minor, and those which are conceptual may be due to ignorance. But I would think one would want to stress the importance of the distribution of lipid findings and values (rather than "abnormalities") their repeatability, the natural history, and the improvement of existing classifications based on these distributions. Obviously this will be sought, but the whole impression given is that the specific "abnormalities" are the important thing. I see you have tried to get the problems in that concept across on page 2, and realize the line you have to tread.

To the justifications on page 3 I would suggest to determine the repeatability of lipid findings, the repeatability of existing lipid classifications, the validity instead of the utility of the existing typology (how do you measure utility?).

It would be very useful to me, and to others if you had available the distribution of total serum cholesterol values according to LDL cholesterol classes, to study the overlapping problem with the Multifactor Trial.

Non-fasting state should be defined. I would like to suggest the group put together the evidence, or quickly run some cross-over controlled experiments, to determine the effect of a glass of juice, coffee (with and without), and/or a cigarette to see whether any of these really preclude a fasting determination, and at what interval after ingestion. This might reduce significantly the recalls.

Cordially,

Henry Blackburn, M.D.

HB/rs

P. S. I add this note, following our site visit. The Minnesota presentation was not effective, though the interest and skills are available.

There was a private comment that you might not continue your role with the LRC. Let me encourage you to do so. I was appalled to see evidence of the lack of communication between branches at NHLI. The LRC is mobilizing a fantastic amount of resources, talent, facilities and population base, and quite aside from some questionable concepts of the lipid classes and a design which will prove the biases of the proponents, there is a serious problem of overlap with the Multifactor prevention concept. It is going to take the strongest leadership to assure that these approaches coexist peacefully and effectively. If I am involved with the Multifactor Trial I will count strongly on working out this question with you.

There are other questions in the proposed design of the intervention trial, and there is a major problem rearing its head in a collaborative study, among the same types of people, using ileal by-pass surgery.

Those responsible for design must be unequivocal in their recommendations, despite the desires of enthusiasts, so that the series of questions needing answers can be most efficiently answered. The NHLI doesn't have sufficient staff strength for this and I hope you will continue to serve this role for the LRC, working in liaison with the other trials now developing.

HB/rs