

university
of
minnesota
memo

OK #3

Jackie

date 3/25 19 75

to Dick Crow
from Henry Blackburn

Thank you for the minutes of your 17 March meeting, which are very good. I am particularly happy to see the high rate of response both at V2 and V3 which represents a change from earlier experience. I really would like to ask for you and Art to submit a definitive protocol on the ear-lobe study or to abandon the effort promptly. I don't think the hypotheses have been well stated, nor the potential for answering useful questions indicated to justify the time, trouble and expense of this, much less an adequate review of the evidence to see whether it is worthwhile at all to instigate such a study. This is a good example of interesting little side lines to excite our intellectual curiosity, but there is no reason to depart from our usual policy of careful evaluation of evidence and careful weighing of proposals before we instigate such studies.

I am sure that you and Art realize what needs to be done in terms of estimated prevalence and incidence rate in our 600 subjects before it can be surmised whether any useful information can be obtained and secondly, that any such study which would involve publication has to be submitted as an ancillary protocol if it involves MRFIT time, personnel and funds.

(over)

This is not to discourage innovation, it is simply to be sure that innovation and curiosity are well considered. Unless a good ancillary protocol with a statement of clear hypotheses and estimates of likelihood of useful results can be made in the next very short period, I would suggest that the matter be dropped and that we simply take the full face photograph. I am concerned that even taking full face photographs might require another consent, which would be a pain in the neck.

A little question came up on Friday between Ron Prineas, Michele and myself, concerning overlapping hypertension and annual visits which we would like to do to accommodate subjects, but which presents certain complications as far as counting and dispensing and prescribing medication. I would appreciate if you would follow up on decisions on this with Ron and Art and be sure that proper criteria of practice on that with, of course, the participant's convenience being of prime consideration.

I thoroughly approve of your point 9 and I suggested some time ago to Haxby that we prepare a brief brochure for people to take home with them and to V2 outlining the points made about the design of the study and the extent of commitment so they can go over it in a written form rather than the usually forgotten verbal form. It is a little late, but I still think the brochure should be put together, and promptly. You might want to check whether Haxby has a first version and I can help expedite it. Thank you.

Point 11. I would like to hear your objections to the quality control function requested of us from the Coordinating Center. I suppose we should cooperate if at all possible.

Thank you for the very good minutes of an obviously constructive meeting.