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Memorandum

To: Trialists

Fr: Curtis Meinert

Re: Farm sociology

Had I known when I enrolled as a PhD student in Biostatistics that my entire professional life would be spent organizing and running multicenter clinical trials, I would have taken courses in sociology and group dynamics. The thing I learned from my first multicenter trial was that I was a stranger in a room full of MDs and that I had to figure out who was who on the fly.

Whatever I know about sociology I learned on the farm.

I learned about pecking order from chickens.

Chickens, when cooped up, will start pecking one another. It does not happen in the summer when they are free roaming. Only after prolonged cooping in the winter. I am not a chicken psychologist, so I have no idea what drives them to peck or how they choose who they peck and I have never seen how it starts, but I have seen how it ends. It is not pretty.

It starts slowly with an occasional peck at the rear of a chicken. Eventually with several taking turns. Once blood is drawn it is too late for rescue. The chicken will die.

You see corollaries in people in late winter. They start bickering and have trouble getting along waiting for spring.

People in groups have pecking orders. Just observe how they interact and who defers to whom for insight on pecking order.

My other sociological lesson was from cows.

It was my job as a young boy to “get the cows” for milking in the summer. Invariably they were in the farthest corner of the pasture when it came time to round them up.

I soon learned if I got the “boss cow” headed home, the others followed in lock step.

Eventually I came to appreciate the order in their society. They always came in the barn in the same order. First the Boss, than the 2<sup>nd</sup> in command on down to most junior.

I did not realize then that those observations would come in handy years later in my first experience in multicenter clinical trials; the University Group Diabetes Program (UGDP).

Except for Chris Klimt (my boss), I was surrounded by strangers. All clinicians who knew one another, but I was a stranger and worse yet, none of them seemed to know what coordinating centers did or even if one was necessary.

I did not have trouble identifying the “boss cow”, but I had no clue as to pecking order among members of the group. For that I had to observe where people sat and who they looked at when they spoke. Eventually I learned there were several boss cows in the UGDP, making for occasional chaos.

A few years later I was involved in running the coordinating center for my second multicenter trial, the Coronary Drug Project (CDP). Unlike the UGDP, the CDP had just one boss cow, Jerry Stamler (see a recent posting of a tribute to him on his death). The contrast between the two structures left a lasting impression as to the importance of decisive leadership in multicenter trials.

Signing on to be a coordinating center is like what Forrest Gump’s mother said about life: It’s like a box a chocolates. You never know what you’re gonna get.

If you know before the trial is funded you will have 2<sup>nd</sup> class status, walk away.

The trouble is that you may not know the structure until after funding. In that case you have to be an active participant in creating the structure. Desired features include:

- Permanent study chair and vice chair; rotating chair generally sign of weak leadership
- Steering committee comprised to include director of coordinating center
- Funding for coordinating center direct from sponsor; indirect funding from chair of study or some other study center not recommended
- Membership on DSMB for coordinating center director
- Parity of membership for director of coordinating center to other leaders of the study group
- Written statements specifying publication and presentation policy of study group and authorship policy