



JOHNS HOPKINS
BLOOMBERG
SCHOOL of PUBLIC HEALTH

Department of Epidemiology
Johns Hopkins Bloomberg School of Public Health
415 N. Washington Street, 2nd Floor
Baltimore, Maryland 21231

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Memorandum

To: Trialists

Fr: Curtis Meinert

Re: High hopes

*Next time you're found, with your chin on the ground
There's a lot to be learned, so look around*

*Just what makes that little old ant
Think he'll move that rubber tree plant
Anyone knows an ant, can't
Move a rubber tree plant*

*But he's got high hopes, he's got high hopes
He's got high apple pie, in the sky hopes*

*So any time you're gettin' low
'Stead of lettin' go
Just remember that ant
Oops, there goes another rubber tree plant
Oops, there goes another rubber tree plant
Oops, there goes another rubber tree plant*

Lyrics from Frank Sinatra's "High Hopes"

The dictionary definition of hope is desire accompanied by expectation of or belief in fulfillment. The hopes and expectations of trialists are modest compared to the ant in Sinatra's High Hopes.

Trials are undertaken to generate knowledge regarding treatments for human conditions. Unlike the ant fixing to move a rubber tree plant on its own, people doing trials are cadres of people fixated on the same objective.

From a personal perspective, joining such a cadre is an act of trust. Its like what Forrest Gump's Momma said "Life is like a box of chocolates, you never know what you're going to get."

Frank Polk's measure of trust was whether he was willing to ride the river with a person. (Billie) Frank Polk came to JHU in 1982 and made his mark as a leader in the AIDS epidemic. He died from a brain tumor in 1988 at the age of 46.)

His rule is intuitively appealing, but impractical because trials can involve 100s of people, many of whom you never meet.

Assuming you meet the tests for membership, there is no guarantee that is true for everyone else. So what do you want of the group you are about to join? My requirements are listed below.

1. Members of the cadre familiar with and adherent to the principles of respect for persons, beneficence, and justice, as set forth in the Belmont Report
2. A group free of financial interests in the trial
3. Unbiased data collection and analysis
4. Dependable, honest, ethical and familiar with and respectful of the IRB process
5. A group supported by staff responsible for quality control and data monitoring
6. Registration of the trial before starting and updating as necessary over the course of the trial
7. How persons are assigned to treatment and when they are counted as enrolled
8. A sponsor willing to fund the trial to completion
9. A sponsor insulated from conflicts of interest
10. A DSMB (Data and Safety Monitoring Board) as needed

Experienced leaders of investigator groups involving dozens of study centers will have training sessions prior to start of the trial and over the course of the trial to reinforce matters of protocol and principles underlying trials.