



Department of Epidemiology
Johns Hopkins Bloomberg School of Public Health
615 N. Wolfe Street
Baltimore, Maryland 21205

14 February 2017

Memorandum

To: Trialists
Fr: Curtis Meinert
Re: Joe DiMaggio?

Where have you gone, Joe DiMaggio?
Our nation turns its lonely eyes to you
Wu wu wu
What's that you say, Mrs. Robinson
'Joltin Joe' has left and gone away
Hey, hey, hey,
Hey, hey, hey
(Last verse in Simon & Garfunkel's "Mrs Robinson")

This was the verse that came to mind when reading *Toward a new era of trust and transparency in clinical trials* (Kathy L Hudson, Michael S Lauer, Francis S Collins; JAMA; published online Sept 16 2016) that henceforth the NIH "will require all applications for clinical trials to be submitted in response to clinical trial-specific Funding Opportunity Announcements (FOA)."

That does not bode well for investigator-initiated trials. As a nation, we have benefitted from the intermixing of investigator and sponsor-initiated trials. It remains to be seen what will happen to investigator initiatives when everything is through funding opportunity announcements.

Years ago I wrote a piece entitled "NIH multicenter investigator-initiated trials: An endangered species? (Controlled Clinical Trials 1988; 97-102). In it I concluded *that it may well be "easier" to wait for RFPs or RFAs for trials than to assume the initiator role, collective compliancy in exercising that role leads us closer to the day where only government will have that "right" and to a world filled with docile trialists. That is not the world that helped make the NIH great in its first 100 years and let us hope it does not characterize that world in the next centennial celebration!*

