JOHNS HOPKINS
UNIVERSITY

Center for Clinical Trials

Department of Biostatistics
Department of Epidemiology
Department of International Health

Department of Medicine
Department of Ophthalmology
Oncology Center

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Memorandum

To: Trialists

Fr: Curtis Meinert

Re: Transparency

Transparency in Webster's is: (1) free from pretense or deceit; (2) easily detected or seen through; (3) readily understood; (4) characterized by visibility or accessibility of information (http://www.merriam-webster.com/dictionary/).

When it comes to trials, everybody wants transparency but nobody knows what it is. If only transparency was like pornography then we would know it when we encounter it (à la Supreme Court Justice Potter Stewart "I know it when I see it" in characterizing his threshold for obscenity in Jacobellis v. Ohio; 1964).

Obama ran on a plank of transparency in 2008, but whatever we got did nothing to quiet his critics.

As a trialist ordained to toil in the lower echelons of life, I strive for transparency but, judging from the ever increasing demands for "transparency", I have fallen short – like Obama.

The International Committee of Medical Journal Editors (ICMJE) in late 2004 announced that:

> *ICMJE member journals will require, as a condition of consideration for publication, registration in a public trials registry. Trials must register at or before the onset of patient enrollment. This policy applies to any clinical trial starting enrollment after July 1, 2005.*

The Committee rationalized the requirement as a step toward transparency.

> *Registration is only part of the means to an end; that end is full transparency with respect to performance and reporting of clinical trials.*

(Never mind trying to figure how barring publication for failing to register promotes transparency!)

The group that produced SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials), came up with the document in the name of transparency.

> *Complete documentation of key trial elements can facilitate transparency and protocol review for the benefit of all stakeholders.*

If transparency is so important, then why not a SPIRIT-like document for meta-analysts and systematic reviews? After all, those analyses and reviews are more important than results of individual trials in reaching conclusions regarding the merits of treatments.

How about a system for registering meta-analyses and systematic reviews in ClinicalTrials.gov or like registries prior to the start of data harvests akin to the requirement for registration of trials prior to initiation.

How about the ICMJE telling us what they do if a trial is not registered prior to the start of enrollment? Of the signatory journals with 2012 publications indexed to publication types [randomized controlled trial] AND [multicenter study] in PubMed and registered in ClinicalTrials.gov (five journals; 201 papers), about one-third were registered after the start of enrollment; 29 six months or more after the date of registration.