



JOHNS HOPKINS  
BLOOMBERG  
SCHOOL of PUBLIC HEALTH

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

25 March 2020

## Memorandum

To: Trialists

Fr: Curtis Meinert

Re: On why not to publish protocols until trials are done

Various groups and authors advocate publishing protocols early in the course of trials during recruitment for “transparency” and as stopgap measures against bias in reporting results later on (e.g., Li T, Boutron I, Al-Shahi Salman R, Cobo E, Flemyng E, Grimshaw JM, Altman DG; *Trials* 18, 34 (2017). <https://doi.org/10.1186/s13063-016-1743-0>).

But protocols change. Just ask anybody doing a trial now in the CoViD-19 pandemic.

The advocates of publication will say one can publish updates when changes occur. True, but normally there are bigger things to do and to be concerned about in the middle of trials, than publishing updates to protocols.

Even under normal times changes occur. In my life as a trialist I have lived through changes to randomization schemes, changes to the primary outcome of interest, treatment stops, clinical holds, and IRB shutdowns, most of which occurred after recruitment was finished. Following the advice put forward by protocol publication advocates would be like publishing baseline results before enrollment is finished.

Like it or not, there are things in protocols that should not be revealed while trials are ongoing as noted in an article entitled *Publishing protocols for trials of complex interventions before trial completion – potential pitfalls, solutions and the need for public debate*; Basu AP, Pearse JE, Rapley T; *Trials* 18, 2017; <https://doi.org/10.1186/s13063-016-1743-0>.

For example, details of the randomization scheme as a protection against investigator bias. If investigators know the randomization scheme, they can predict assignments. For example, if the blocking scheme for a two treatment trial is two and treating investigators know the blocking scheme, they can predict half the assignments before issue.