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Memorandum

To: Trialists

Fr: Curtis Meinert

Re: Protocols

A protocol in the jargon of trials is a written document specifying purpose of the trial, eligibility requirements, treatments being tested, method of assigning treatment to treatment units and details of data collection and followup. In everyday usage often used as a synonym for treatment, as in "on protocol".

A written protocol is one of five principal documents needed for conduct of a trial. The others are

Participant consent form,
Manual of operations (aka MoO or MOO),
Policy and procedure memorandums (PPMs),
and
Data collection forms.

All five should be available to the public on request.
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Protocols are akin to those glossy pages in cooking magazines with pictures of appetizing dishes. They tell you what goes into them but lacking details needed to master them. To make the dishes you need detailed recipes and practice. That "recipe" in trials is represented by the MoO, PPMs, and data collection forms. If you want to know what goes on in trials you need those three documents. The protocol will give you information in broad strokes, but it is not a blue print for the trial.

SPIRIT, *Standard Protocol Items: Recommendations for Interventional Trials* (5 February 2013; *Annals of Internal Medicine*) provides a list of 33 items that should be covered in study protocols.

Registrants on ClinicalTrials.gov can post study protocols but few do. Of the 241,181 trials registered as of 4 May 2019 less than 2% had protocols posted. The percentage is the same for the 132,136 trials logged as competed.

The NEJM posts protocols as supplemental material for trials it publishes. Of the 133 papers indexed in PubMed as [randomized controlled trial] and published in 2016, all but three had protocols posted. Length, measured by page counts ranged from 8 to 832 for the 130 publications. The ranges and median number of pages by funding source are given in the table below.

Protocols

Funder	No.	Pages: Range	Pages: Mdn no.
US govt	28	8 - 238	73
Non US govt	34	12 - 332	48
Industry	47	24 - 832	86
Foundation	24	14 - 322	56
Totals	**133**	**8 - 832**	**73**