



8 May 2013

## Memorandum

To: Trialists

Fr: Curtis Meinert

Re: My rules as a trialist

You spend a career doing trials and you end up with rules. Here are mine. What are yours?

**Rule 1:** Don't get involved in trials with numbers in the name

*Comment:* This rule is a variation of one for my kids to stay away from movies with numbers in the title because they are not as interesting as the originals. The same can be said for numbered trials.

**Rule 2:** Don't get involved in trials with co-primary outcomes

*Comment:* This rule is also a corollary to one I taught my kids, namely, to not ride on airplanes with two co-pilots instead of a pilot and co-pilot.

**Rule 3:** Strive to equalize the slop between treatment groups

*Comment:* Randomization is the crème de la crème slop equalizer. Masking helps. Treatment comparisons are valid so long as the slop across treatment groups is equal.

**Rule 4:** Expect it to take twice as long to enroll half the number planned and expect the event rate in the control group to be half that expected

*Comment:* The rule of twos!

**Rule 5:** Don't do pilot studies

*Comment:* Pilot studies are as much work as the real thing so go whole hog or not all.

Early in my career I decided I did not want my tombstone to read "Here lies a guy who did pilot studies but nothing definitive".

**Rule 6:** Don't get involved with a group if you have to explain what you do

*Comment:* The rule is important for someone like me in the coordinating center business. Most people don't understand what they do.

**Rule 7:** Steer clear of groups intent on presenting first and publishing later

*Comment:* See "On publish first, present later", posted to [trialsmeinertsway.com](http://trialsmeinertsway.com), for why I am the way I am on this issue.

**Rule 8:** It is not decided until it has been debated and voted three times

*Comment:* I learned this reality in my first trial – the University Group Diabetes Program (UGDP). It took three votes over two months for investigators to agree to stop use of

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tolbutamide in the trial. This pattern repeats when forging authorship and publication policies. Don't count the issues settled until the third vote and then expect groups to weasel on the policy when there are results to publish.

**Rule 9:** Have workarounds to keep groups from making precipitous protocol changes

*Comment:* Except for issues of safety, it is unwise to make a change without a "cooling off period" and an "environmental impact analysis" before a final vote.

**Rule 10:** Don't send papers for publication if the last oops is less than three weeks old

*Comment:* An oops in paper writing is something out of the blue that comes to you in the middle of night, while on the way to work, or in the hallway talking to a colleague. They usually present in the form "Did I take account of ..." or "Did I check ...". An oops can be career ending, like discovering the treatment groups in a paper just published are mislabeled.

**Rule 11:** Haste makes waste

*Comment:* Everybody is in a hurry. People in coordinating centers know that when it comes to getting started! "We need to get on with enrollment. How hard can it be to produce a few data collection forms and a data system?"

Rush and you will enroll ineligible. Who do you see about that?

**Rule 12:** Strive to make new mistakes

*Comment:* Making new mistakes is progress. Repeating old ones is a sign it is time to do something else.

Posted to [trialsmeinertsway.com](http://trialsmeinertsway.com)