JOHNS HOPKINS
BLOOMBERG
SCHOOL of PUBLIC HEALTH

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

6 February 2019

Memorandum

To: Trialists

Fr: Curtis Meinert

Re: Robert's Rules of Order and clinical trials

Henry Martyn Robert (1837–1923): born in Robertville (named after the Robert family), South Carolina, raised in Ohio, graduated from West Point (1857) as a military engineer, and buried in Arlington National Cemetery. Robert is best known for his Manual of Rules of Order for Deliberative Assemblies (also known as "Robert's Rules of Order"); published 1876; loosely patterned after parliamentary rules of the U.S. Congress.

Henry Robert was stimulated to produce his rules of order after presiding over a meeting in the First Baptist Church, in New Bedford, Massachusetts. The meeting disintegrated into open conflict over the issue of slavery. Mr. Robert resolved to be better prepared by knowing more about parliamentary procedure before the next meeting.

Anybody who has presided over a group of trialists at a research group meeting will recognize the similarly between church meetings and meetings of trialists.

I was moved to write this piece when a colleague, Janet Holbrook, sent me an article about Henry M Robert III, grandson of Henry Martyn Robert. She knows that I have often extolled the virtues of students knowing the basics of Robert's rules if they plan lives as trialists.

I became a devotee of Robert's Rules of Order after my first experience in trials – the University Group Diabetes Program. Meetings in that group were akin to Robert's in the First Baptist Church in New Bedford.

UGDP investigators were like every other group new to trials; scoffing at the need for rules. Whenever the issue was raised, it was summarily dismissed in the belief that rules were unnecessary, secure in the belief that key decisions would be by consensus. But consensus went out the window in Robert's first church meeting and in the UGDP when faced with its decision whether to stop the use of tolbutamide as a study treatment.

The UGDP investigators were an unruly bunch. The best that could be hoped at meetings was for no more than three to be talking at the same time. If anyone was familiar with Robert's Rules of Order it was not apparent and, indeed, when someone attempted to restore order by citing one of his rules the citation was more likely to produce debate about the rule than order. Yet this same group, when convened by conference telephone, was polite and conversations were orderly, with only one person speaking at a time. This difference in behavior led me to suggest, during a particularly chaotic meeting, that the group retire to their respective rooms and have the hotel arrange a conference call.

The fateful day came in June 1969 when the Steering Committee was faced with an up or down vote on whether to stop use of tolbutamide. The voting policy was two votes per center – two for each of the twelve clinics and two for the coordinating center (a vote for the center director and for the deputy center director) – but without any policy on proxy votes, "stand in" votes, designation of

"deputy director", or size of vote required for a decision. The ambiguities were noted when the policy was drafted, but considered unimportant because voting would be unnecessary in the expectation that major decisions would be by "consensus". Consensus is wonderful, but is certain only in groups of size one.

The first vote was close: 13 stop; 12 continue. After a show of hands there followed a debate as to who had voting rights, sort of a precursor to the "hanging chad" problem of the 2000 presidential election in Florida.

There is no issue more central to conduct of any research activity than who has responsibility for writing up results of the research, who will be listed as authors, and order of listing. Experience with proposals for authorship in investigator groups is that the first time a proposal is presented it is greeted with silence, almost as if the group cannot be bothered with such mundane matters. The second time the proposal is greeted with a few polite comments. The third time the issue produces meaningful debate and discussion and it really gets interesting when there is a paper to write.

Some weeks back a colleague asked what I would have in a curriculum for students being groomed to manage trialist research groups. One of the modules I would require would be an introduction to Robert's rules. I warned my colleague about glassy eyes but that students would thank him for the primer later on.

So instead of a gathering at the First Baptist Church, in Massachusetts, suppose your job is trying to ensure order in a multicenter group of trialists. What are the issues you need to address? Key questions follow.

Who belongs to the investigator group?

Just because somebody was at the meeting in Robert's Baptist church did not mean the person was a member of the church. The same is true for persons at research group meetings of trialists.

So what defines an investigator in the trial? A functional rule of thumb is a person is an investigator if associated with a study center performing a function in the trial.

Who has voting rights?

Knowing a little something of churches, I suspect that not all members of Robert's Baptist Church had voting rights. I know, for example, when I grew up in Sleepy Eye, that women did not have voting rights in the German By God Lutheran Church we attended (irritating my Mother no end). I would not be surprised if the same was true for women in Robert's church.

Trialists research groups are usually reluctant to address the issue of voting because they (naively) assume consensus will prevail and that voting will be unnecessary and because of concerns akin to those of my Mother's for persons denied votes.

The practice when groups get to the issue of voting is to limit votes to persons who have line authority over the trial. In the UGDP there were votes for the center and deputy director of each of the 12 clinics and coordinating center. The practice of limiting votes to "principal investigators" meaning heads of clinical centers is not recommended because it makes second class citizens out of other center directors, like those of coordinating centers.

Who should be in charge of the investigator group?

The principal investigator in single center trials and the chair of the study in multicenter trials.

Who should speak for the study?

The issue arises when there are queries from the press or public regarding the trial. The pastor in Robert's Baptist church spoke for the church. By analogy the principal investigator in single center trials, but who if is multicenter? The answer depends on the nature of the question. If the question is specific to a particular center than usually a responsible person from that center. If the question is about the trial than the chair or deputy chair of the study. The usual practice in multicenter trials that

have addressed the issue is to instruct center directors on questions or issues they can address and those that are to be referred to a designated study spokesperson.

Who governs the research group?

In a single center trial usually a small cadre of people loosely characterized as study officers, e.g., the principal investigator (PI), the PI deputy, and the person responsible for data analysis. In multicenter trials usually a group officially designated as a steering committee with representation from each center in the trial or a subset of centers when the number is too large to provide a seat for each center. For example, in the Coronary Drug Project with 55 clinics and a coordinating center a combination of permanent and elected (rotating) members.

What should the publication policy of the group be?

Chances are this question will be far down the list of questions for groups starting trials. If you are in charge of trying to keep order in the group you will have to force them to address the issue before there are papers to write. Key issues are whether to allow presentation of primary results before publication (Recommended policy: Publish first; present later) and whether to allow interim publication of results as the trial proceeds (Recommended policy: absolutely not)

Who should be listed as authors on key publications?

This issue is always contentious, even in single center trials. Fashioning a fair policy in multicenter trials involving dozens of centers requires the wisdom of Solomon and the patience of Job. The policy should be addressed before there are papers to write. It is too late to address the issue with meaningful discussion with papers in the ante room.

The preferred approach is corporate forms of masthead listings for papers having ten or more eligible authors. The model to be avoided, if authors are named, is one involving only heads of clinical centers.

How are votes on key issues taken and what size vote is required for major decisions to carry?

Key issues include adding or stopping a treatment in an ongoing trial, implementing major protocol changes such as changes in the enrollment criteria, changes in the way the primary outcome is defined or measured, changes in sample size requirements for the trial, or changes in the length of treatment and followup.

The story about votes to stop use of tolbutamide in the UGDP underscores the need for explicit voting rules before groups are faced with major decisions such as stopping a treatment. The rules should be clear on how votes are taken (open or closed?) and issues for which more than a simple majority is required.

Who sees interim results?

The policy on who in the study sees interim results by treatment group should be established before there are results to see. Typically, because of worries concerning treatment related biases, investigators seeing study patients do not see interim results.

If there is a data and safety monitoring board (DSMB) who appoints it and to whom does it report?

Increasingly the practice is for sponsors to appoint the board and have it report to them. Investigators will resist the practice since the board serves both the sponsor and investigators. That dual responsibility is threatened when the sponsor owns and operates the DSMB.