JOHNS HOPKINS
U N I V E R S I T Y

Center for Clinical Trials

Department of Biostatistics
Department of Epidemiology
Department of International Health

Department of Medicine
Department of Ophthalmology
Oncology Center

(Thursday) 25 January 2001

Memorandum

To: Center faculty, staff, and friends

Fr: Curt Meinert

Re: Advantages of the corporate form of authorship for results papers from trials

This is the eighth in a series of memos concerning issues in the presentation and publication of results from trials. Previous memos have dealt with the obligation to publish, investigator right of primacy, limits to that right, type and place of publication, deposit of finished datasets, presentation of results at scientific meetings, and internal presentation of results.

The general formats for authorship in trials are:

Corporate: Masthead attribution to the research group; writing committee not identified (Masthead listing: The Serum Rhubarb Clinical Trials Research Group; Writing committee: Not identified)

Modified corporate: Masthead attribution to the research group; writing committee listed (Masthead listing: The Serum Rhubarb Clinical Trials Research Group; Writing committee (footnote to title page or one of the committees in the credits listing): CL Meinert, S Tonascia, and B Collison)

Conventional: Authors listed in the masthead of the paper; no reference to the study group (Masthead listing: CL Meinert, S Tonascia, and B Collison)

Modified conventional: Authors listed in the masthead of the paper and the name of the research group (Masthead listing: CL Meinert, S Tonascia, and B Collison *for* the Serum Rhubarb Research Group; or CL Meinert, S Tonascia, and B Collison *and* the Serum Rhubarb Research Group)

The conventional format is favored as can be seen in the table below. The vast majority of the papers from multicenter trials published in NEJM and JAMA in 1998, 1999, and 2000 (through October 15th) had a conventional or modified conventional authorship format (205 out of the 219; 131 conventional and 74 modified convention).

The tendency is not surprising. Researchers like to see their names in mastheads of papers – a relish independent of age and rank.

Promotions committees like the format because of the tendency to regard authorship position as an indicator of scholarship and independence. The more papers with the candidate as the

sole author or, failing that, then as the lead author, the better. They are prone to discount corporately authored papers because they are "authorless".

Editors prefer the format as well. The preference is the result of the "laboratory model" of research. The model is predicated on the supposition that the work reported was conceived of and done by the people listed and, therefore, that authorship signifies "ownership". They dislike the corporate format because it does not fit the model. Indeed, the editors of the NEJM have gone so far as to ban the corporate format (NEJM 21 Nov 1991; 325:1,510-1,512), but without success. From the first full year of the ban, 1992, through 21 November 2000 there have been 42 multicenter trials published under the corporate format (15 modified corporate) in the NEJM.

Author formats of multicenter trials*

	1998			1999			2000			Total		
	NEJM	JAMA	Tot	NEJM	JAMA	Tot	NEJM	JAMA	Tot	NEJM	JAMA	Tot
Numbers												
Conv	10	15	**25**	8	15	**23**	10	16	**26**	**28**	**46**	**74**
Mod conv	37	13	**50**	35	12	**47**	20	14	**34**	**92**	**39**	**131**
Corp	4	0	**4**	1	0	**1**	1	1	**2**	**6**	**1**	**7**
Mod corp	1	1	**2**	0	0	**0**	4	1	**5**	**5**	**2**	**7**
Total	**52**	**29**	**81**	**44**	**27**	**71**	**35**	**32**	**67**	**131**	**88**	**219**
Percentages												
Conv	19.2	51.7	**18.2**	30.9	55.6	**32.4**	28.6	50.0	**38.8**	21.3	52.3	33.8
Mod conv	71.2	44.8	**79.5**	61.7	44.4	**66.2**	57.1	43.8	**50.7**	70.2	44.3	59.8
Corp	7.7	0.0	**2.3**	4.9	0.0	**1.4**	2.9	3.1	**3.0**	4.6	1.1	3.2
Mod corp	1.9	3.4	**0.0**	2.5	0.0	**0.0**	11.4	3.1	**7.5**	3.8	2.3	3.2
Total	**100**	**100**	**100**	**100**	**100**	**100**	**100**	**100**	**100**	**100**	**100**	**100**

* Results of PubMed search performed in mid October 2000; multicenter trials identified by publication type; author format classified by inspection of the papers; counts provided by Winifred Werther

Invariably, one of the arguments advanced for the conventional format is that it is needed to help young people in the trial build creditable CVs. In another life perhaps, but the harsh reality in long-term treatment and prevention trials is that they are unlikely to do much for one's CV, regardless of how papers are authored. The likelihood is that the promotions clocks will have chimed (or tolled) before there is anything to list. The time from start of enrollment to the first results papers in completed trials coordinated by people in the Center for Clinical

Trials is listed below (see memo *On the type and place of publications* in this series for more details).

University Group Diabetes Program (UGDP)	9 yrs
Coronary Drug Project (CDP)	8 yrs
Hypertension Prevention Trials (HPT)	8 yrs
Glaucoma Laser Trial (GLT)	7 yrs
Childhood Asthma Management Program (CAMP)	7 yrs
Coronary Drug Project (Aspirin) (CDPA)	4 yrs
CMV Retreatment Retinitis Trial (CRRT)	4 yrs
HPMPC Peripheral Cytomegalovirus Retinitis Trial (HPCRT)	3 yrs
Foscarnet-Ganciclovir Cytomegalovirus Retinitis Trial (FGCRT)	2 yrs
Monoclonal Antibody Cytomegalovirus Retinitis Trial (MACRT)	2 yrs

If there is any thing to be taken from the list above it is that you should stay away from long-term trials if you need publications for promotion and, if you find yourself in trials, that you should concentrate on trials likely to stop early (the case for all four of the CMV retinitis trials listed).

The other harsh reality is that listing in the masthead of papers is usually reserved for "big shots". Junior people, unless they head centers in a multicenter trial, are not likely to make the "cut" for conventional listings. If you doubt that this is so, check a few listings from multicenter trials. Most of the "authors" in conventional listings are reserved for directors of centers and members of the leadership body of the trial.

An obvious difficulty with the conventional format in large-scale multicenter trials is in the numbers of "authors" listed in the masthead. The median number of authors for multicenter trials published in JAMA and NEJM in 1998, 1999, and 2000 runs from 7.5 to 12 (range: 2 to 33); see table below.

Journals limit the number of persons that can be listed in the masthead of manuscripts. The NEJM (Information to authors; 6 January 2000) specifies that for multicenter trials *No more than 12 names will be listed under the title; other names will appear in a footnote*. For example, an article entitled *Treatment of Acromegaly with the Growth Hormone-Receptor Antagonist Pegvisomant* (NEJM 2000;342:1,171-1,177) lists 33 authors, the first 12 of whom are listed in the masthead of the article and the other 21 of whom are listed in a "Other authors were" footnote on the first page of the article.

Similarly, in citations to papers, an author needs to be near the head of the list, eg, among the first six on papers cited in the NEJM, to be listed (all other authors are "et al" in NEJM citations). In regard to listings in MEDLINE, rules have varied over the years. From 1966 - 84, NLM indexers listed all authors, regardless of number. From 1984 - 95 indexers limited

listings to 10 authors with additional authors indicated by an "et al" listing. The limit was 24 for 1996 - 99. There is no limit for year 2000 publications to present.

The author field is blank or contains the note "no named authors" in the NLM listings for corporate publications. The members of the writing committee are listed in the author field with the modified corporate format.

Number of authors for papers from multicenter trials*

	1998			1999			2000			Total		
	NEJM	JAMA	Tot	NEJM	JAMA	Tot	NEJM	JAMA	Tot	NEJM	JAMA	Tot
Conventional format												
# of pubs	10	15	25	8	15	23	10	16	26	28	46	74
Mdn # authors	11.5	9		7.5	9		12	8				
Min	4	2		6	2		7	4				
Max	12	16		10	19		33	16				
Modified conventional format												
# of pubs	37	13	50	35	12	47	20	14	34	92	39	131
Mdn # authors	11	8		11	10		12	10				
Min	3	5		3	1		2	4				
Max	19	15		21	18		17	23				
Totals												
Conv	10	15	25	8	15	23	10	16	26	28	46	74
Mod conv	37	13	50	35	12	47	20	14	34	92	39	131
Corp	4	0	4	1	0	1	1	1	2	6	1	7
Mod corp	1	1	2	0	0	0	4	1	5	5	2	7
Totals	**52**	**29**	**81**	**44**	**27**	**71**	**35**	**32**	**67**	**131**	**88**	**219**

* See footnote to table above

A question that has to be addressed by groups whenever the conventional format is used is "Whose names do we list?" Ultimately, someone has to decide. Will the order be by "contribution" or seniority? Should the listing be alphabetic, reverse alphabetic, or random?

The debate and discussion regarding who gets listed and the order of the listing can be contentious and divisive. Coming to an answer can be difficult, especially when the number of names exceeds the limit imposed by the journal. Even if the limit is not exceeded, there will be "jockeying" for position in the listing because of the value attached to position.

The emotion and heat generated in such discussions can be reduced if the rules for listing and ordering are set well in advance of any paper writing activity. But, why not avoid the issue entirely by opting for the straight, unmodified, corporate format for mainline papers[4]? In many senses, it is the best option among imperfect options.

It is the fairest and most accurate way of characterizing work that is the product of a corporate activity. If the work is the product of a corporate activity, is it not fair and proper that it be published under a masthead conveying that characterization?

It is issues of accuracy and fairness that drives me to the straight, unmodified, corporate format of attribution in multicenter trials. Where is the fairness in listing certain people as authors while others, equally deserving and qualified, are bypassed? Basically, the conventional format in multicenter trials is to the benefit of a few at the expense of many.

The requirements for authorship under the Vancouver Convention uniform requirements for manuscripts submitted to biomedical journals specifies that each person listed as an author must have made a substantial contribution to *(a) conception and design, or analysis and interpretation of data; and to (b) drafting the article or revising it critically for important intellectual content; and on (c) final approval of the version to be published. Conditions (a), (b), and (c) must all be met.*

International Committee of medical Journal Editors
Uniform requirements for manuscripts submitted to biomedical journals
New Engl J Med 336:309-315, **1997**

A person has license to list in one's CV any corporately authored publication where the conditions of authorship are met. That license in multicenter trials, when conventional formats are used, is voided for all except those named as authors in the masthead listing.[5] Even if

[4] Papers detailing the design, methods, or baseline results of a trial or containing original results related to the primary objective of a trial and written by study personnel commissioned by the investigative group or their representative.

[5] A workaround to provide some degree of equity in regard to authorship credits when conventional formats are used is to have a system of "rolling" authors in the hope, that when all is said and done, that every qualified person will be listed in at least one publication. The trouble with

one accepts the fact that promotions committee are prone to discount corporately authored papers, they do not ignore them. For certain, when going in front of promotions committees, it is better to have a CV containing such citations than one devoid of them by virtue of being denied license to cite because the person's name does not appear among the "authors" listed in mastheads of papers.

The other major reason for objecting to formats involving named authors (including the modified corporate format) is what they lead to in the way results are cited by others – invariably by the first author; *Jones et al* or *Jones and co-workers*. Why should a multicenter trial involving a cast of 100's be forever attributed to Jones or Jones and co-workers when Jones was just one among many and when Jones may not have even been around when the trial was started?

A downside with the straight corporate format is that editors may require letters of attestation from all members of the research group listed in the credit roster because they are all regarded as "authors". That requirement is limited to persons named in the writing committee or persons named in the masthead in conventional authored papers.

The job of obtaining such letters can be tedious but also has hidden advantages. The letters serve to document participation and "buy-in" in regard to the finished results and conclusions. The likelihood of "minority" reports coming from disgruntled members of the research group after the paper is published is diminished by the buy-in and sign-off process.

In any case, however, the task of collecting letters of attestation from the entire research group is not unique to the corporate format. The modified conventional listing, especially the *and the XYZ Research Group* form, is likely to require letters of attestation from all members of the research group as well.[6]

It is possible to win the battle and lose the war when trying to get groups to opt for the corporate format for mainline papers. The problem will be getting them to accept the straight,

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such systems is that not all papers are created equal. It is better to be listed on a mainline primary results paper than on an also run paper. The other problem is that there is no guarantee that there will be enough papers to go around. The number will depend on the energy level of the group and the duration and success of the trial.

[6] In theory, the license to list in one's CV exists with this form of attribution even if one is not listed as an author, but the practice is likely to be seen as questionable by promotions committees because the person is not a named authors.

unmodified, corporate format. There is a fair chance, if they give up on conventional formats, that they will tilt in favor of the modified corporate format.

The truth is, however, that that format is not much better than the conventional formats. Listing people, even if only in a footnote to the title page, raises all the issues discussed above as to who is listed and the order of listing and means, as well, that the license to list in one's CV, as discussed above, is voided for all except those named. It means also that the writing committee will be regarded as authors when the paper is indexed by the NLM, as noted above.

The discussion here relates to papers containing the primary results of a trial and other related mainline papers. The recommended approach is to move to the modified corporate format for papers containing results of secondary relevance to the trial, to the modified corporate or modified conventional format for papers of tertiary relevance to the trial, and to the modified conventional or straight conventional format for papers containing results of ancillary studies.