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

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Memorandum

To: Center for Clinical Trials faculty and staff

Fr: Curt Meinert

Re: Publication and presentation good practice policies and procedures (GPPP)

Definitions

acknowledgment *n* - 1. An expression of appreciation or thanks for something done or contributed or for a kindness given. 2. A written expression of such appreciation or thanks, eg, as appearing in a **published manuscript**. rt: **credit**

authorship *n* - 1. The source of a work, such as a **manuscript**. 2. The state or act of creating or writing, especially in relation to something written. ***Usage note***: See **Vancouver Convention** and **authorship attribution**.

authorship attribution *n* - The persons, **group**, or **agency** to which a work is **attributed**. See **conventional authorship** and **corporate authorship**. ***Usage note***: The requirements for attribution under the **Vancouver Convention** of **uniform requirements for manuscripts submitted to biomedical journals** are that it *should be based only on substantial contributions 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.* (New Engl J Med 336:309-315, **1997**)

ancillary publication *n* - [**research**] 1. A **publication** containing original **ancillary results**. 2. A publication bearing on an ancillary **aim** or **objective** of a specific **research project**; in the case of **trials**, usually publications devoted exclusively to results form **ancillary studies**. rt: **primary publication**, **secondary publication**

autonomy, right of *n* - The **right** to be self-governing or self-directing without outside control.

big trial *n* - 1. A **trial** having a **sample size** of 1,000 or more per **treatment group**; a trial having a per treatment sample size severalfold larger than that of similar trials heretofore done or reported. 2. A trial having a large **number** of **centers**, a large number of investigators, or involving a large outlay of money compared with other related trials. syn: large trial rt: **big and simple trial** ***Usage note***: Avoid as a generic label without accompanying detail to indicate sense of usage. Often that which is **big** or **large** from one perspective is ordinary from another

perspective; hence, the term is not informative by itself without explanation. Note as well that defn 2 has a different connotation than defn 1. Defn 1 relates to sample size, whereas defn 2 relates to other dimensions of the trial and may be used even if the sample size is not big in the sense of defn 1. See **big and simple trial** for additional comments.

credit *n* - [MF, fr OIt *credito*, fr L *creditum* something entrusted to another, loan, fr neut of *creditus*; pp of *credere* to believe, entrust] 1. Recognition by name of some person, **group**, or **agency** for having performed specific functions or duties in relation to some activity, project, or production. 2. Such a recognition appearing in print in a published **manuscript** or at the start or end of a film. rt: **acknowledgment**

conventional author *n* - A person responsible for writing some **document**, such as a **manuscript**, and who is identified as an **author** in the **masthead** or title of a work. ant: **corporate author**

corporate author *n* - A **corporate** entity, such as an **agency**, **institution**, or **collaborative group**, designated as **author** of some work; usually in the absence of named individual authors in the **masthead** of papers. See *author/authorship* for list. ant: **conventional author** rt: **corporate author citation**

modified conventional author citation *n* - 1. A form of **conventional author citation** in which, in addition to individuals, the **corporate** entity (or entities) under which the work was done is named in the **masthead** or title of a work (eg, Nancy Jones and Harry Brown for the XYZ Research Group). 2. Such a citation in a **bibliography** or **reference list**. ant: **modified corporate author citation** rt: **conventional author citation**

modified conventional authorship *n* - A form of **authorship** involving named **authors** and a **corporate** entity in the **masthead** listing of authors; see **modified conventional author citation** for example. rt: **modified corporate authorship**

modified corporate author citation *n* - 1. A form of **corporate author citation** in which the names of the individuals responsible for writing the work on behalf of the **corporate** entity appear in a footnote to the title page or in the **credits** or **acknowledgments** section of the work. 2. A citation in a **bibliography** or **reference list** in which individual names appear in relation to a corporate work. ant: **modified conventional author citation** rt: **corporate author citation**

modified corporate authorship *n* - A form of **authorship** in which the **masthead attribution** is to a **corporate** entity (eg, the XYZ Research Group), but where **authors** are listed elsewhere in the work (in the **credits** or **acknowledgments** section or in a footnote to the title page). rt: **modified conventional authorship**

presentation *n* - 1. A work displayed (as in a poster session) or read at a professional meeting. 2. The act of **presenting**; something **presented**. 3. Something disseminated for the purpose of

generally informing but not a **publication** (defns 3 and 4). rt: **publication** ***Usage note***: **Presentation** and **publication** have overlapping connotations to the extent that both terms relate to displaying or presenting for the purpose of informing. Hence, in the broad sense of use, a presentation can be characterized as a form of publication. Avoid **presentation** if **publication** (defns 3 and 4) is appropriate. See **present**, **publish**, and **publication** for additional comments.

primacy, right of *n* - The **right** of being first. In regard to **trials**, the right of those who collect the **data** and carry out the trial to be first to **present** or **publish** (prior to making or being required to make data available to others for interpretation or **analysis**).

primary result *n* - [**research**] A **result** (defn 3) of direct relevance to the primary **objective** of a **study**. In **clinical trials**, a result based on the **primary outcome measure** or on the **design variable** of the trial. rt: **secondary result**, **ancillary result**

publication *n* - [ME *publicacioun*, fr MF *publication*, fr LL *publication-*, *publicatio*, fr L *publicatus*, pp of *publicare*, fr *publicus* public] 1. The act or process of **publishing**. 2. A published work. 3. A **manuscript** appearing in an **indexed journal** (print or electronic). 4. A print document or its electronic equivalent appearing in a **book**, proceedings of a meeting, or other similar compendium, as normally found in a library or residing in an **electronic database** open to public use. rt: **presentation**, **interim publication** ***Usage note***: **Publication** has connotations overlapping those of **presentation**. Publication, in the **research** setting, is best reserved for use in relation to defns 3 and 4. See **publish**, **present**, and **presentation** for additional comments.

publication bias *n* - 1. An inclination or tendency toward **publication** of results that support conclusions favoring a particular **hypothesis** or position. 2. Any influence or factor that results in a differential inclination or tendency toward publication, regardless of whether related to the nature or direction of **results** (eg, influences or factors such as gender of the investigator, source of funding for the study, or specific design and operating features of the study). ***Usage note***: Most usages are in the sense of defn 1 and are offered in a speculative or cautionary sense (as opposed to a declarative sense) in that demonstration of the **bias** is often difficult or impossible. The **bias** (defn 1) operates when the decision of investigators to prepare a paper for publication is influenced by the nature or strength of the conclusion that can be drawn from the results, or when referees and editors of the journals base their decisions for acceptance or rejection on the statistical importance of the results or on the nature of the conclusions stated or implied by the results. The supposition for **trials** is that the bias is more likely to operate in trials not showing any difference (**nil result**) than for those showing a difference, and among those showing a difference the bias is assumed to be more likely for trials producing **negative results** (defn 2) than for those producing **positive results**. The bias, if operating, has serious implications for **meta-analysis**. Usages in the sense of defn 2 are quite different from those for defn 1 and should be noted as departing from the conventional definition of the bias. In the sense of defn 2, the reference is to any factor influencing publication, whether or not related to the nature or

direction of results, including those fixed before or when the study is started, such as the age, gender, or rank of the investigator, or type or source of funding.

secondary publication *n* - [**research**] 1. A **publication** containing original **secondary results**. 2. A publication considered essential in relation to a secondary **purpose** or **objective** of a specific **research project**; in the case of **trials**, usually publications devoted exclusively to results for a **secondary outcome measure** or publications providing added information bearing on a **primary result**. syn: **secondary paper** rt: **primary publication**, **ancillary publication**

study credit roster *n* - A list or roll of names of persons, institutions, businesses, agencies, or organizations having some role, function, or association with a **study**; such a list as appearing at the end of a **study manuscript**.

study curriculum vitae *n* - A tabular-like listing, akin to that of the **curriculum vitae** of a person, relating to a **study**; containing historical facts concerning the study and a listing of significant accomplishments, including a listing of **presentations** and **publications** emanating from the study. rt: **curriculum vitae**

Vancouver Convention *n* - The set of rules and specifications relating to **authorship attribution** and **manuscripts** submitted for publication to biomedical **journals** (see **uniform requirements for manuscripts submitted to biomedical journals**); named for the site of the first meeting of journal editors held in Vancouver, British Columbia in 1978; see **authorship attribution** for Vancouver Convention requirements for authorship.

P&P 1: Establish policy on publications and presentations when the trial is designed.
Comment
The time for setting policy is at the outset. The worst time is when it is time to start writing.

P&P 2: Provide ample time for discussion and deliberation in the SC before policy is presented for vote.
Comment
Policy proposed and voted upon at the same meeting generally makes for bad, nondurable, policy.

P&P 3: Commit policy to writing and circulate to investigators.
Comment
It is not policy until it is written and circulated.

P&P 4: Review and revise policy as necessary over the course of the trial.

P&P 5: Establish policy consistent with investigator right of autonomy and right of primacy.
Comment

The investigators' right of autonomy is abridged if sponsors have a say in what is published or when something is published. The investigators' right of primacy is abridged if the policy does not ensure that investigators are first in line to publish.

P&P 6: In regard to manuscripts being prepared for presentation at a scientific meeting or for publication, accord sponsors the right of review, but not the right of approval.

Comment

According sponsors right of approval is counter to P&P 5.

P&P 7: Sponsors' right of review should be time limited.

Comment

Without a time limit, sponsors have de facto veto rights on manuscripts and hence capable of violating P&P 5.

P&P 8: The number of days allotted a sponsor for review should not be more than 30 days for manuscripts containing primary results; less in cases where there is urgent need to publish.

P&P 9: Do not accept funding agreements having clauses serving to abridge the investigator right of autonomy or primacy.

Comment

Clauses in funding awards or agreements having that effect can be "deal breakers" in academic institutions. Officials of academic institutions are not likely to accept funding with constraints on publication.

P&P 10: In NIH funding in which the Institute Director or some other official of the Institute assumes the right of review of manuscripts as a condition for submission, produce a written agreement, signed by an official of the Institute and an officer of the study, that indicates that right of review does not convey right of approval, the allowable time for review, and that investigators may proceed to submission without such review if not done within the allowable time.

P&P 11: Establish policy committing investigators to timely publication of primary results regardless of the direction or nature of those results.

Comment

One can argue that investigators are the recipients of a public trust by virtue of having been granted the privilege of being able to conduct research on human beings and that that trust is violated if they fail to publish.

P&P 12: Publish primary results in peer-reviewed, MEDLINE indexed, journals.

Comment

Publications not indexed in MEDLINE are, for all intents and purposes, "lost" and, hence, at best, make only marginal contributions to the world's knowledge base.

P&P 13: In regard to primary results, publish first, present later.

Comment

The impact of the P&P is to commit investigators to spend their energies on producing publishable manuscripts. Operationally, the P&P means that primary results are not presented prior to publication. The reasons underlying the P&P have to do with the realities that: (1) The best and most effective method of communication is via published manuscripts in indexed journals; (2) Presentations are ineffective means of communication in that they reach a limited few; (3) Presentations divert energy from preparation of publishable manuscripts; (4) Questions and concerns raised by presentations cannot be adequately addressed in the absence of published manuscripts; (5) Presentation first increases the time to publication (4 to 6 months as suggested in dissertation work by Aynur Ünalp of the Center for Clinical Trials).

P&P 14: Define classes of papers to be generated; specify authorship format and internal review procedures for the classes.

Comment

Suggested classes, measured against objectives of the trial, are:
Primary
Secondary
Ancillary

P&P 15: Gravitate to the corporate or modified corporate form of authorship for primary manuscripts; gravitate to the modified corporate or modified conventional format for secondary manuscripts, and gravitate to the modified conventional or straight conventional format for ancillary manuscripts.

Comment

The corporate form of authorship is preferred for studies involving a large number of investigators and in multicenter trials involving 6 or more centers. The format eliminates the "jockeying" for position that is likely to occur whenever authors are named, whether in the masthead or in a footnote (as with the modified corporate form of authorship).

P&P 16: Be specific when proposing the modified conventional format as to whether the masthead attribution will be the "*for*" or "*and*" format (ie, Nancy Jones and Harry Brown *for* the XYZ Research Group, or Nancy Jones and Harry Brown *and* the XYZ Research Group).

Comment

The "*and*" format generally leads editors to regard the entire research group as authors and, therefore, to require letters of attestation from all members of the group, whereas letters are required only from Jones and Brown if the "*for*" format is used.

P&P 17: Be familiar with requirements for authorship as set down in the Vancouver Convention.

Comment

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**

P&P 18: In regard to primary results, forego "orchestrating" presentation to correspond with publication.

Comment

The temptation, invariably, is to try to have one's cake and eat it too. "Why not schedule to present at the next meeting of the "Whatyoucallit" Society. After all, the meeting is 9 months off. Surely that will be more than enough time to have a paper accepted for publication and for it to be in print by the time of meeting!" If you buy that, see me about a bridge I have for sale in Brooklyn. Things never go as planned, especially when it comes to paper writing.

Most attempts at timing are futile. The schedule of review, revision, resubmission, proofs, and publication of manuscripts is not predicable and, in any case, proceeds independently of dates for presentation. The most prudent policy is to forego presentation prior to publication.

P&P 19: Impose a system for internal review and approval of abstracts submitted for presentation and for invited presentations concerning the study.

Suggestions

- Establish in conjunction with publication policy
- Indicate domain of coverage; indicate if review and approval is required for presentations related to information already published; indicate if presentations limited to factual matters concerning the study, as contained in the protocol or in related study documents, such as data collection forms, study handbooks, or consent forms, require review and approval
- Establish procedures for review of presentations (typically, review in multicenter trials is done by study officers); if policy is laissez faire (ie, policy where abstracts may be submitted prior to review), require submitter to withdraw abstract if not approved in review

P&P 20: In regard to a system for P&P 19: Do not impose review requirements for presentations involving information regarded as being in the public domain.

Comment

Persons involved in multicenter trials do not leave their first amendment rights at the door. They should not be more constrained than ordinary citizens in regard to what they can know or say about facts of the trial. If the information they are presenting is not privileged, they should not be subjected to study review. Broadly, this means that information regarding design or operating features detailed in study documents and available to the public should be available to study investigators to present as they see fit.

P&P 21: Regardless of the policy on presentation versus publication of primary results, ensure that investigators are informed of results before they are presented or published.

Comment

The P&P is implicit in the right of primacy. Special efforts may be required to ensure adherence to the policy in multicenter trials when it is necessary to stop or alter the trial based on review of interim results by a TEMC.

P&P 22: Setup procedures to ensure that patients are informed of results prior to presentation or publication, especially in cases where results have treatment implications.

Comment

The requirement is an implicit part of the unwritten contract investigators make with patients when they enroll. It is a violation of patient trust if they learn of important results from news reports.

P&P 23: Establish and maintain a study CV containing information on history and funding, dates of meetings of the study officers, SC, research group, and TEMC, and a listing of study committees (standing and ad hoc) and their memberships, in addition to a listing of all study publications, abstracts, and presentations.

P&P 24: Create and maintain a credit roster; list participating institutions and associated personnel; list committees and membership; maintain so as to provide a cumulative list of all centers and associated personnel, past and present.

P&P 25: Write prototype acknowledgments for inclusion in study manuscripts; statement should list funding agencies and contributions to the trial in form of gratis drugs or supplies.

P&P 26: Establish procedures for commissioning papers, for appointing writing committees and chairs, for monitoring progress of commissioned papers, for decommissioning writing committees, and for reconstituting nonfunctional or nonproductive committees.

P&P 27: Establish systems to avoid exceeding the capabilities of the CC to support commissioned papers.

Comment

A useful rubric is to limit the number of active commissions to some number, eg, 4, in the "4 burner stove" model – A model in which no more than 4 papers are in active production at any time. New commissions are held until a manuscript comes off a "burner" (ie, is submitted for publication or is decommissioned).

P&P 28: Establish procedures for internal review of papers prior to submission; done by study officers or by a standing or ad hoc reviewer panel.

P&P 29: Establish policy for titling of study manuscripts and implement procedures to ensure compliance.

Comment

Ideally, titles should include the name of the trial and currency words such as *trial*, *randomized*, *controlled*, and *masked* (when applicable), words indicating the nature of the treatments being tested, and words indicating the disease or condition being treated.

P&P 30: Decide whether papers are to be numbered.

Comment

The advantage to numbering is in clues to readers. If a reader comes across paper #4, the reader is clued to the existence of 3 other papers.

A word of caution: The numbers will not be sequential if assigned and affixed when papers are submitted for publication.

P&P 31: Establish a repository for published papers in the CC or Office of the Chair.

P&P 32: Designate an office or person within the trial having responsibility for distributing published papers to study investigators, the TEMC, and sponsor(s).

P&P 33: Set up and maintain procedures to check tables and analyses contained in study papers prior to submission or presentation.

P&P 34: Establish procedures to ensure documentation of analyses contained in papers submitted for publication and for storage of datasets supporting those papers.

P&P 35: Establish policy aimed at making finished dataset available to the public.

Comment

Generally the best and most reliable way of meeting this goal is by depositing data in a public archive on a paper-by-paper basis. The difficulty with waiting to the "end" of the trial for deposit is that the "end" can come at any time and, generally, if premature, the likelihood is that people will be more interested in finding their next job than in readying datasets for deposit.

P&P 36: Establish rules and procedures for freezing datasets for paper writing.