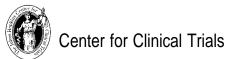
JOHNS HOPKINS

U N I V E R S I T Y



Department of Biostatistics Department of Epidemiology Department of International Health Department of Medicine Department of Ophthalmology Oncology Center

(Friday) 15 December 2000

Memorandum

To: Center faculty, staff, and friends

Fr: Curt Meinert

Re: Memos for trialists concerning presentation and publication of primary results and mainline papers from trials

Definitions (fr Meinert; *Clinical Trials Dictionary*)

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

mainline paper n - [trials] A paper 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. syn: primary publication rt: secondary paper

primary publication *n* - [research] 1. A publication containing original data, especially one containing a primary result. 2. A publication from a study or *investigation* considered essential in relation to the primary purpose or objective of a specific research project; in the case of trials, includes publications of primary results and on the design, methods, and baseline results of the trial. syn: mainline paper rt: secondary publication, ancillary publication

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

secondary paper *n* - **[trials]** A **paper** dealing with a secondary **objective** and written by study personnel commissioned by the **investigative group** or their representative. syn: **secondary publication** rt: **mainline paper**

The series of memos to follow (first of which attached) are prompted by discussions regarding policy on publication of results in trials. Having worked with dozens of groups in "birthing" multicenter trials, I know, sooner or later, that groups have to come to grips with questions concerning when and what to present and publish.

This series of memos is predicated on the belief that:

- 1. Investigators assume a moral obligation to publish when they undertake a trial
- 2. Investigators should not undertake a trial if they lack the right of primacy
- 3. Results should be published in peer-reviewed, MEDLINE indexed, journals
- 4. Datasets from trials should be made available to the public when papers are published or when the trial is finished
- 5. Results should not be presented prior to publication (publish first, present later)
- 6. Results in multicenter trials should be published under the corporate form of authorship
- 7. Titles for primary manuscripts should include the study name and the term *trial* or *randomized trial*
- 8. Papers should include credits and acknowledgments

\PubPol\PresPub.WPD