

## **9. PUBLICATIONS POLICY – APPROVED JANUARY 15, 2005**

### **9.1 Philosophy**

The purpose of the publication policy is to:

Encourage the timely preparation of high quality publications and presentations from NICHD Global Network for Women's and Children's Health Research studies.

Promote academic recognition of participants who make significant contributions to the NICHD Global Network for Women's and Children's Health Research.

### **9.2 Governance of the Publications Subcommittee**

#### Membership

The subcommittee has 4 to 6 Steering Committee members; members will be selected by the NICHD Global Network for Women's and Children's Health (GN) Director in consultation with the Global Network Chair. Members will serve 3-year terms (these may be extended at the discretion of the NICHD GN Director and the member). The subcommittee will select a chair who will serve a 3-year term. In addition, the NICHD GN Director, the Data Coordinating Center (DCC) Principal Investigator and the Steering Committee Chair serve as subcommittee members.

#### Quorum

A quorum for a meeting or conference call consists of the presence of 4 subcommittee members (including the Subcommittee Chair and NICHD representative).

The subcommittee reports to the Global Network Steering Committee.

### **9.3 Authorship**

Authorship for GN publications will follow the International Committee of Medical Journal Editors' (ICMJE) Guidelines:

#### **ICMJE Authorship and Contributorship**

##### ***II.A.1. Byline Authors***

An "author" is generally considered to be someone who has made substantive intellectual contributions to a published study, and biomedical authorship continues to have important academic, social, and financial implications. The International Committee of Medical Journal Editors has recommended the following criteria for authorship; these criteria are still appropriate for those journals that distinguish authors from other contributors.

- Authorship credit should be based on 1) substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data; 2) drafting the article or revising it critically for important intellectual content; and 3) final approval of the version to be published. Authors should meet conditions 1, 2, and 3.
- When a large, multi-center group has conducted the work, the group should identify the individuals who accept direct responsibility for the manuscript (3). These individuals should fully meet the criteria for authorship defined above and editors will ask these individuals to complete journal-specific author and conflict of interest disclosure forms. When submitting a group author manuscript, the corresponding author should clearly indicate the preferred citation and should clearly identify all individual authors as well as the group name. Journals will generally list other members of the group in the acknowledgements. The National Library of Medicine indexes the

group name and the names of individuals the group has identified as being directly responsible for the manuscript.

- Acquisition of funding, collection of data, or general supervision of the research group, alone, does not justify authorship.
- All persons designated as authors should qualify for authorship, and all those who qualify should be listed.
- Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content.

Some journals now also request that one or more authors, referred to as "guarantors," be identified as the persons who take responsibility for the integrity of the work as a whole, from inception to published article, and publish that information.

Increasingly, authorship of multi-center trials is attributed to a group. All members of the group who are named as authors should fully meet the above criteria for authorship.

The order of authorship on the byline should be a joint decision of the co-authors. Authors should be prepared to explain the order in which authors are listed.

#### *II.A.2. Contributors Listed in Acknowledgments*

All contributors who do not meet the criteria for authorship should be listed in an acknowledgments section. Examples of those who might be acknowledged include a person who provided purely technical help, writing assistance, or a department chair who provided only general support. Financial and material support should also be acknowledged.

Groups of persons who have contributed materially to the paper but whose contributions do not justify authorship may be listed under a heading such as "clinical investigators" or "participating investigators," and their function or contribution should be described - for example, "served as scientific advisors," "critically reviewed the study proposal," "collected data," or "provided and cared for study patients."

Because readers may infer their endorsement of the data and conclusions, all persons must give written permission to be acknowledged.

(Source: *Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publication*: [www.icmje.org](http://www.icmje.org); updated November 2003)

### **9.3.1 Disputes in Authorship**

The collaborators in a study should first discuss disagreements about authorship. The authors should review the criteria for authorship during such discussions. If disputes still exist, the matter may be taken to the Publications Subcommittee. The resolution should be based on the above guidelines and any authorship guidelines that exist for the particular journal or outside collaborators. Unresolved disputes concerning authorship should be documented in a memo to the NICHD GN Director.

### **9.3.2 Acknowledgment of support**

For presentations and publications emerging from grant-supported activities of the grants, investigators are legally required by NIH to acknowledge the funding sources from NIH and other groups. Generally, the acknowledgement will take the following form:

Financed by the Global Network for Women's and Children's Health Research (NICHD U01 HD\*\*\*\*\*, U01 HD\*\*\*\*\*, ...) and the Bill and Melinda Gates Foundation.

(This is an example. Other institutes or funders may be cited, as appropriate.)

## 9.4 Review Process

### 9.4.1 Objectives

The Publications Subcommittee will review all publications with the following objectives in mind:

to ensure that no publication will have a harmful effect on the study process, on study acceptance by the research community or relevant groups, or on the interpretation of study results;

to prepare comments to assist collaborating scientists to publish papers of the highest quality (the latter is accepted as a responsibility because all publications related to Global Network research will affect public perception of its scientific rigor and operational activities);

to correct factual and conceptual inaccuracies;

to safeguard the rights of volunteer study subjects;

to inform the Steering Committee, NICHD and Data Monitoring Committee of all public dissemination of information; and,

to ensure appropriate acknowledgement of funding.

### 9.4.2 Review process

The Global Network has a common review process for all abstracts, presentations and manuscripts which is as follows:

1. **The GN study must be registered prospectively on <http://www.ClinicalTrials.gov>.**
2. The primary author should ensure that the publication has been reviewed and approved by all authors (including the senior statistician of the DCC and the collaborating NICHD Program Official) prior to submission to the Publications Committee. The primary author should include a statement to this effect with the submission.
3. All publications must be reviewed by the GN Publications Subcommittee prior to publication. This should be initiated at least 4 weeks prior to applicable deadlines; however, it is strongly recommended that authors submit publications to the Subcommittee as soon as possible to allow time for revision if major changes are recommended.

The Publications Subcommittee Chair or his/her designee will assign reviewers. Primary reviewers will return written comments to the primary author and to the GN Publications Committee with a recommendation as follows:

Accept as is  
Accept with revision  
Major changes recommended

If a reviewer has major concerns, he or she can request further discussion by the GN Publications Committee.

For publications, reviews will be provided to the author within two weeks. For

presentations and abstracts, reviews will be provided to the author within two days.

4. Following revision based on the GN Publications Subcommittee review, the author should submit the revised version (with a track-change version and/or a memo outlining the changes) to the GN Publications subcommittee. The same members will re-review it, whenever possible.
5. Following approval of the publication by the Publications Subcommittee, the author should submit the publication in its final format to the collaborating NICHD Program Official for NICHD clearance (if a publication has been “accepted as-is” it will be submitted directly for NICHD clearance).
6. Following NICHD clearance, the author should submit the abstract/manuscript to the meeting or journal. A final copy of all manuscripts and abstracts should be forwarded to the GN Publications Subcommittee coordinator and NICHD GN Director for archival purposes.

#### **9.4.3 Presentations to Local Professional Groups**

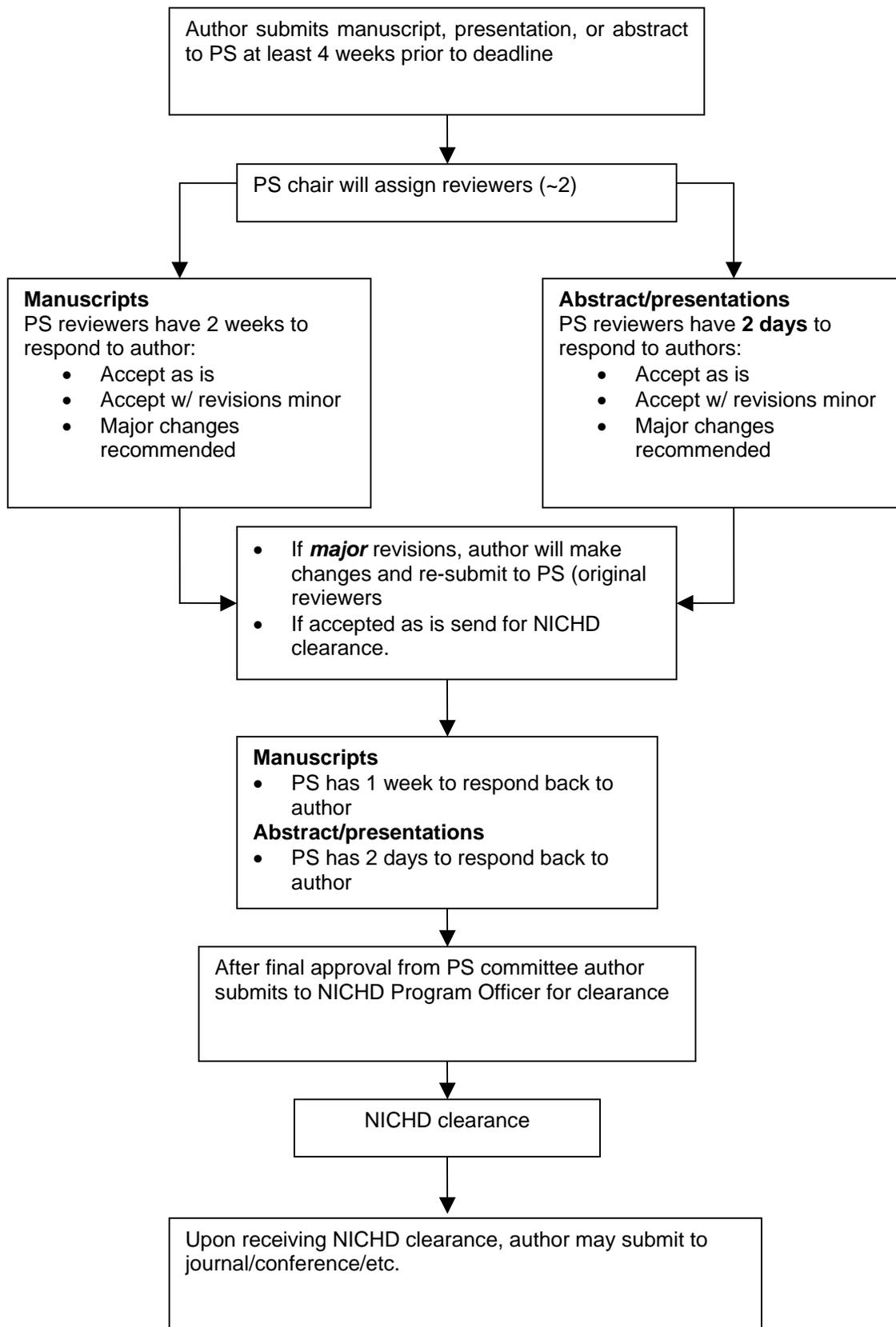
It is expected that investigators will be asked to make presentations to local professional or political groups. If the presentation describes study design, training, infrastructure, or other aspects of study implementation at the local site, no permission is needed to give the presentation, although NICHD and the DCC should be notified of the presentation. If the presentation involves baseline or outcome data, the presentation should be reviewed as described above.

#### **9.4.4 Pre-publication Interviews, Press Releases, and Press Relations**

A press release is defined as a document given to radio, television, newspapers, and popular periodicals without national circulation or scientific journals not indexed in Index Medicus. NICHD press releases will be coordinated by the GN Program Director in collaboration with the PI, the DCC, and the NICHD Office of Research Reporting. An interview is any discussion with a member of the press, a science writer or radio or television commentator that in turn provides information for public dissemination. Press releases and interviews will not be initiated by the collaborating Research Units unless they comply with the specifications below.

If a Research Unit or DCC investigator is asked for a press release or interview, it may be given without prior review and approval by the Steering Committee, provided the substantive content is limited to information available either in the original grant application, the final protocol, or the Manual of Operations, with no added interpretation or inferences. A copy of each prepared release as well as the final publicity available, e.g. published article, tape of interview, etc., will be forwarded to the NICHD GN Director and to the DCC. If the collaborating site is asked for information other than that detailed above, the site should refer organization or individual making the request to the GN Publications Committee Chair.

### Publications Subcommittee (PS)—Flowchart of Review Process



**Appendix: Publications Subcommittee Members and Staff**

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