



October 2005

Publication, Authorship, and Presentation (PAP) Guidelines

Global Network for Perinatal and Reproductive Health (GNPRH)

Goals of GNPRH PAP Guidelines

- Facilitate preparation and completion of high quality publications and presentations from GNPRH studies.
- Provide appropriate academic/authorship recognition to participants who make significant contributions to the research agenda and activities of the GNPRH.
- Encourage GNPRH investigators and members of the faculty of centers part of the GNPRH to develop research protocols and use the support and resources of the GNPRH for the advancement of the research agenda at their centers and their professional careers

Publication, Authorship, and Presentation (PAP) Committee

The Publication, Authorship, and Presentation (PAP) Committee is responsible for governing all matters related to publications, authorship and presentations resulting from network protocols. The committee will consist of no more than eight investigators representing the geographical distribution of the GNPRH centers. Each member will serve a term of 3 years. Membership in the committee will be based upon successful previous participation in a GNPRH study or protocol development. All the investigators part of the GNPRH are eligible to be members. Membership in the committee will consist of:

- GNPRH Steering Committee Chairperson
- Co-coordinator(s) of GNPRH
- 6 Investigators representing the geographical distribution of the GNPRH centers

The Current Members of the authorship committee are: Jorge E Tolosa MD MSCE- coordinator of the GNPRH, Oregon health & Science University, USA; Pisake Lumbiganon MD MS- coordinator of the GNPRH, Khon Kaen University- Thailand; Tsungai Chipato MB, ChB Department of Obstetrics and Gynecology, University of Zimbabwe; Mario Festin MD- The University of the Philippines; Sheela Shenoy MBBS, MD- Associate Professor , Trivandrum, Medical College, India; Katherine Ba-Thike, Institute of Medicine, Yangon, Myanmar, Hernando Gaitán, Director CEU, Universidad Nacional de Colombia and Sean Daly, Master and CEO Coombe Women's Hospital, Ireland.



Definitions

- **Main Protocol:** A study designed prospectively by a committee for implementation independent of other network protocols. It is proposed by a member of the GNPRH who is the P.I. for the study. The protocol is prepared by the committee, led by the P.I. for the study.
- **Ancillary Protocol:** Designed by a center's PI or other key personnel at a center in conjunction with the development of a main protocol that does not interfere with the hypothesis or implementation of the main protocol.
- **Pilot Protocol:** Preliminary study that will generate data for design of a main protocol. A pilot protocol involving two or more GNPRH centers must be approved by the GNPRH coordinators.
- **Primary Analysis:** Analysis of the primary outcomes as described in the protocol
- **Secondary Analyses:** Analyses based on secondary outcomes stated within the protocol or based on other concepts not included in the protocol as agreed by the steering committee members.
- **Additional Analyses:** Analyses conducted after all primary and secondary analyses have been conducted by the network investigators. These happen after the database has been opened to the participating centers, once the manuscripts and reports for the study have been accepted for publication. The decision to open the database is made by the members of the steering committee for the study and the decision is informed to the PAP committee, which approves "opening" of the study database. Additional analyses will only involve the analysis of each center's own data. Any additional analyses involving two or more centers must be approved by the GNPRH PAP committee.
- **Steering Committee:** Each study will have a protocol steering committee which consists of the primary author of the protocol and other investigators who must contribute significantly to the development of the protocol. The primary author of the Protocol (lead PI) will serve as the chair of the committee. Each participating center in the study will have a co-P.I. who will have a seat at the protocol/study steering committee. The Chairperson in consultation with the other members, can include other investigators in the committee, who would have no voting powers in the decisions of the committee.
- **The Data Management and Biostatistical Coordinating Team (DM-BCT):** is based at Oregon Health & Science University where the main office of the GNPRH is located. The DM-BCT will work closely with other centers taking part in specific studies to facilitate transference of skills and foster collaboration between investigators and centers part of the GNPRH. The DM-BCT will be responsible for the maintenance of the study database, the coordination of data collection with study sites, the primary and secondary analysis and data management of the study in general. Data management and analysis are responsibilities of the P.I.

Analysis Procedures

Main Protocol

- **Primary Analysis** is based upon the primary outcomes stated within the protocol.

The analysis plan for the Primary Analysis is stated in the protocol. After data lock, the Principal Investigator is responsible for data analysis with the DM-BCT. All co-P.I.'s need to be involved with the analysis of the data, as part of the Steering committee duties.

- **Secondary Analyses** are based upon secondary outcomes stated within the protocol or based on other concepts not included in the protocol.

Secondary analysis will be determined by the protocol committee. Requests for Secondary analysis not outlined in the main protocol, should specify the objective, database to be used, the population, the outcome of interest and the proposed analysis. Requests must be sent to the Steering Committee Chair who will work with the DM-BCT in prioritizing the requests and will reviews such requests with the committee members who must approve. Requests for secondary analysis from GNPRH databases must be made by the GNPRH center P.I. or can be made by any member of the faculty at a GNPRH center, with support of the center P.I.

GNPRH Investigators who sponsor requests from colleagues for secondary analysis from their own institutions are expected to endorse the scientific merit of the request, ensure that the PAP guidelines are followed and coordinate communication with the DM-BCT.

- **Additional Analyses:** Once the main manuscripts and reports from a GNPRH study have been completed and accepted for publication, the study Steering Committee will decide when to “open” the database. Once the database is “opened” each center receives a copy of the data generated by that center. **Additional analysis** are based upon each centers own data and may not include any additional centers without the approval of the PAP committee.

Ancillary/Pilot/Special Protocols

In multi-center studies, the DM-BCT will collaborate with the Protocol Chairman and Protocol Steering committee to provide the analysis of the data and prepare abstracts and/or manuscript for publications.

In the case of a single center ancillary study, the center conducting the study will be responsible for the analysis and reporting of the results. Abstracts and manuscripts resulting from data from the single center which uses a GNPRH protocol is subject to the



review process outlined in these guidelines. If data from any other center is included or is requested from the DM-BCT, a request signed by all investigators involved and must be submitted to the PAP committee and follow the review procedures outlined in these guidelines.

Priorities for Data Analysis

The Study Steering Committee will be responsible for assigning priorities and scheduling data analysis in conjunction with the DM-BCT. Primary Analysis will be given the highest priorities, with Secondary analysis prioritized by the PI of the study in agreement with members of the Steering Committee.

Approvals, priorities, and scheduling of analysis will be disseminated to the proposers of the request and the Steering committee in a tabulation that will be updated periodically.

If disagreements emerge the PAP will suggest and approve requests, assign priorities, and coordinate scheduling.

Time Lines

Analysis

Approximately 2 months post- completion of follow-up of subjects (when applicable), the database will be “locked” and no further data updates will be accepted from the centers. This date will be defined by the study Steering Committee. The Steering Committee Chairperson is responsible for setting a timeline, to ensure that there are no unnecessary delays. After data lock, the data will be analyzed for the primary outcomes.

Final Report and Manuscripts

A draft of the final Report will be submitted to the Protocol Steering Committee within six months after data lock. Comments from the Protocol committee will be accepted by the DM-BCT and revisions made over a one-month period. The P.I. for the study will oversee that all manuscripts related to the study follow this timeline and will work with the assigned primary author for each manuscript planned from a study. After that, the final report will be distributed to the PAP committee for their expedited review and comment before submission to the selected journal.

Ideally, the number of manuscripts that are to be produced from the study should be defined at the time of completion of the protocol and before the study is initiated. This proposal should be made by the study P.I. to the Steering Committee for the study. As there are factors that cannot be determined before the study is completed, which might affect the contribution of individuals to the project, (enhancing or decreasing it), as well as limitations defined by the journal to where the manuscript is to be submitted, the



number of co-authors and order of authorship in the manuscripts will NOT be defined a-priori.

Choice of Journal

Once the Study Steering Committee has assigned responsibility for authorship, the primary author has responsibility for selecting the journal for manuscript submission. Once the author has selected the journal for submission, a proposal has to be submitted to the protocol steering committee for final approval and presented to the PAP committee. Consideration of author limitations should be a factor in the selection, in order to maximize recognition of Network participants. Ideally journals selected will be indexed and will follow a peer-review process.

Authorship

Main Protocol

- Abstracts: Authorship will include the name of the presenting author and as many co-authors as allowed by the scientific meeting where the work will be presented and will include the statement, “for the Global Network for Perinatal and Reproductive Health”.
- Primary Analysis: eligibility for authorship will include the following:
 - Protocol Steering committee (Each center participating in a study will have a person from the center listed as a primary co-author)
 - Other participating center co-investigators and consultants
 - Co-coordinators of the GNPRH
 - GNPRH Program Officer
 - “And the Global Network for Perinatal and Reproductive Health (GNPRH)”

The chair of the protocol Steering committee will be the first author of the main report and recommend the order of authorship for the remaining members of the protocol committee in an order consistent with their efforts to the PAP committee. The PAP with direction from the protocol steering committee chair, will then approve the order of the remaining authors based on the following criteria:

- Level of contribution determined by a standard authorship documentation form
- Significant participation in conceptual development and writing of the protocol
- Active Participation and communication via conference calls, study meetings, and emails
- Consistent data quality from the center
- Monitoring of performance of site co-PIs and key personnel by the center P.I.
- Participation in the analysis and interpretation of data
- Successful recruitment of study participants in accordance with sample size

- Involvement in the development and preparation of abstracts and manuscripts. In an effort to list only appropriate authors, the Study Steering Committee Chair will distribute a questionnaire to each possible co-author requesting that they document their contributions to the study and to the manuscript using a standard authorship documentation form. If their contribution cannot be documented, they will not be listed as authors. A letter to the journal will be sent at the time of the manuscript submission, which will document the contributions of each author.

With approval of the Steering committee for the study, at any time in the study before the database is locked, the center PI's can relinquish their authorship to a colleague from their institution, assuming that person has contributed to the project as outlined before. A letter explaining the reason for this decision needs to be sent by the center P.I. to the PAP committee. Generally, only one GNPRH investigator will be listed from each institution. **It will be a decision of the center P.I., which member of the investigators involved in the study from the specific center will be listed as a co-author. All others will be listed in the acknowledgement section.**

Decisions on co-authorship of scientific reports prepared by each center, using the data generated by that center are made by that center P.I.

The protocol Steering committee may also recommend that consultants making significant scientific contributions to the study be credited as authors; such recommendations will be made by the Chair of the Study Steering Committee.

The remaining participating center authors will be listed in an order based on ranking recruitment number, accuracy of data, and adherence to the study protocol. Each occurrence of overdue forms related to the study, inaccurate data, and divergence from study protocol will be recorded and tabulated according to the table presented below. The average score of all the numbers will serve as the score of that center and centers with lower scores will receive preference for authorship over those with higher scores.

Example Table (This is a guideline of how these matters can be weighed for final decisions which will be made on a case by case basis for each study)

Center	Accuracy Rank	Recruitment Rank	Number of Overdue Forms	Total Rank	Overall Score
A	1	2	0	3	2
B	2	2	1	5	3
C	3	5	0	8	3
D	4	4	2	10	4
E	5	3	5	13	5

If the editor requires fewer authors, the choice of which authors to include will be made by the protocol steering committee following a suggestion made by the study P.I. If there



is no agreement, the Steering Committee chair will consult with the PAP and all members of the study will accept the recommendations of the PAP. Co-authors in the specific manuscript who are also members of the PAP committee will remove themselves from being involved in the deliberations and decisions made by the PAP. Priority will be given to Steering committee members and always the number of authors will be maximized, even by contacting the editor of the selected journal to request special considerations to include the largest possible number of authors.

If there is disagreement that cannot be overcome, in spite of mediation by the PAP, the PAP will recommend corporate authorship (no specific authors except for the GNPRH) and submission of the manuscript will be completed. The previously assigned first author for the manuscript will complete the manuscript, which will be reviewed by all members of the study steering committee and forwarded to the Chair of the PAP who will submit the manuscript for publication.

Ancillary Protocol

Single-center Ancillary: If accomplished at one GNPRH center, the authorship of an ancillary study will include the PI of the ancillary protocol and the Chair of the Protocol Steering committee (for the main protocol). Other authors in the study will be determined by the PI of the ancillary protocol and will be approved by the Study Steering Committee.

Multi-center Ancillary: Ancillary studies involving more than one center in general involve significant input from the GNPRH network and DM-BCT. Consequently, these studies require establishment of a subcommittee and adherence to the PAP guidelines outlined for primary protocols. The PI of the main protocol will be credited as a member of the Ancillary Protocol Steering committee.

Pilot Protocol

Pilot data can be published as a separate manuscript, IF APPROVED BY THE STUDY STEERING COMMITTEE AND THE PAP Committee, in which case the PI of the pilot protocol will be first author. The list of authorship will include the members of the protocol Steering committee.

Change in Protocol Steering Committee Chair

Although Network participants may change during any particular study, and for the purposes of authorship, the protocol Steering committees chairman identified at the time of the study approval will ordinarily continue in this capacity for the duration of the study. However, if the Steering Committee Chair and the Co-coordinators of the



GNPRH determine that an individual is unable to continue participation, chairmanship will be assigned to the individual from the Steering committee who has been most active in the study. The original chairman will be credited as an author if he/she has contributed significant to the design, conduct, analysis, or publication of the study.

Acknowledgments

The support of the granting body and organizations, institutions, universities supporting the activities of the GNPRH will be acknowledged on all manuscripts at the foot of the title pages “this work receive financial/other support from (insert granting body)”. Manuscripts will include an appendix containing an acknowledgement of all regular GNPRH staff (including the DM-BCT) and other individuals making significant contributions to the study that are not credited as authors (e.g. research nurses, laboratory personnel, etc.), and the subjects recruited into the study. The P.I. at each center will submit such suggestions to the Chairperson of the Protocol Subcommittee or to the person responsible for manuscript preparation.

In the case of corporate authorship, the writing committee will be acknowledged separately and clearly.

Publication of Manuscripts and Abstracts

All manuscripts and abstracts must be approved by the Protocol Steering Committee and authors prior to submission to the chair of the PAP committee. The PAP committee will then review (in an expedited manner) and approve or comment on manuscripts and abstracts before submission to journals or societies for publications or presentation.

Manuscript Review:

Once a manuscript is submitted by the Study Steering Committee Chair to the PAP Committee, the chairman of the PAP will conduct a critical review of the manuscript or abstract and can ask specific members of the PAP Committee or members of the Technical Advisory committee (TAC) for the GNPRH who are not authors or other scientists, to perform an ad-hoc and expedited review of the manuscripts or reports.

Written reviews (approximately one page) are faxed or emailed to the chair of the PAP committee and the primary author no later than the third Friday after receiving the manuscript or abstract for review. Base upon these reviews, the author resubmits a revised manuscript along with the reviewer’s comments to the PAP committee Chair.

A conference call will be scheduled by the GNPRH program officer for the approval of the manuscript. The Program Officer will distribute the manuscript and the reviewer



comments. The call will include the first author, the DM-BCT, the primary reviewers, the PAP chair, the Co-coordinators of the GNPRH, and the Program Officer and consultants as needed.

The manuscript is revised as indicated by the discussion on the conference call and submitted to the journal. Once the manuscript is revised for the journal, final copies are sent to all authors by the primary author.

The primary author will fax or email galley proofs to the co-authors, PAP chair, the coordinators of the GNPRH and to the Program Officer.

Review of Abstract:

The Chairman of the PAP Committee will conduct a critical review of the abstracts, submitted by the first author, along with the PAP and Study Steering committee. A conference call will be scheduled by the GNPRH Program Officer within one week preceding abstract deadline, to include the author, reviewers, Chair of the PAP committee and GNPRH coordinators to approve the abstract for submission. Other authors and Study Steering Committee members may request to be included in the conference call when the abstracts are being reviewed. Comments are provided to the author on this conference call. An alternative method of communication such as electronic mail or fax can be used as well to maximize the number of people who are involved in the process and want to contribute with their suggestions.

Public Presentation

The results of GNPRH studies should not be discussed publicly before publication or presentation in a peer-reviewed forum. Following this presentation, results can be presented publicly with prior approval of the PAP committee (The Coordinators of the GNPRH can serve as a proxy for the PAP committee for this purpose). Following presentation of an abstract, discussion should be limited to data already reported. Describing results as preliminary may help to avoid subsequent conflicts with journal policies for manuscript publication.

Public presentations at participating centers limited to describing study protocols, background, relevance, and previously published results are encouraged. With the same limitations, the GNPRH coordinators can approve media interviews and other public presentations on a case-by-case basis if this is deemed to be in the best interest of the GNPRH.



Oral and poster presentations, including those resulting from secondary analyses at professional societies must list all participating institutions and, if this differs, all institutions within the GNPRH.

All public presentations and publications of data by individual investigators and centers should be reported to the GNPRH office, to be included in a database of activities of the GNPRH.

Public Access to Data Collected in GNPRH Studies

Primary analysis and multiple primary analyses for descriptive studies and secondary analyses of databases of studies conducted by the GNPRH will be limited to GNPRH investigators subject to the policies outlined above, for two years following the distribution of the Final Report.

All investigators must provide the DM-BCT with funding required to perform analyses after two years or they can perform their own analysis.

After that time, other investigators outside the GNPRH may apply for analysis to the DM-BCT, with endorsement of an GNPRH investigator and subject to approval of the Steering PAP Committee.

Five years after the primary manuscript has been published, the data set and necessary documentation will be made available at cost by the DM-BCT for analysis by any investigator outside the network. These will be provided at no cost to GNPRH investigators on request.

After the database for a specific study had been “opened”. A copy of the data will be sent by the BCT to each center. If a specific center wishes to perform analysis on a GNPRH database involving more than one center, the guidelines outlined before need to be observed.

Exceptions and Changes

These guidelines are intended to establish effective routines for publication and to address the very difficult issues of academic and authorship recognition that will result as part of studies done by multiple centers and involving many investigators and co-investigators. From time to time, the need for exceptions due to unusual circumstances or permanent changes to improve the policy may arise. These should be submitted to the PAP Committee, who will forward the request along with their recommendation to the GNPRH Steering Committee. The GNPRH co-coordinators, in conjunction with the PAP



committee chair, can approve urgent exceptions to the PAP policy. All changes and most exceptions to these guidelines will require approval of the GNPRH Steering Committee.

As the GNPRH will work with organizations and institutions which have their own authorship and publications guidelines as well as recommendations about ‘ownership’ of data, the GNPRH will work to secure agreement between the study investigators and those organizations or institutions.

The guidelines will need to be approved by the GNPRH coordinators, all the P.I.’s at each one of the centers part of the GNPRH, by each one of the P.I.’s at each center before the start of a study and by the members of the PAP committee. Suggestions on how to improve these guidelines will be requested from the TAC members of the GNPRH and other are welcomed and should be directed to the Coordinators of the GNPRH, Jorge Tolosa or Pisake Lumbiganon.

Participation in GNPRH activities is voluntary. These guidelines should serve as an instrument to facilitate what to date has been a successful cooperation between individuals who share a common vision and goals. As the activities of the GNPRH get more complex, result of the success of the previous efforts made by a large number of people involved with the GNPRH, it is expected that use of the guidelines will be needed, to assist in the completion of important research activities and growth of the investigators part of the GNPRH

Respectfully submitted,

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