Longitudinal Assessment of Bariatric Surgery (LABS) Consortium
Publication and Presentation Subcommittee Mission Statement

Propose to the Steering Committee a formal policy for presenting and publishing LABS data including preparing manuscripts, assigning tasks in analysis and writing, writing group membership, authorship, internal review, and other issues related to abstracts, presentations, and publications. The policy will cover full manuscripts, abstracts, and other publications and presentations. The process will be developed to ensure that study results are disseminated in a timely, accurate, and clear manner.

Longitudinal Assessment of Bariatric Surgery (LABS) Consortium
Publication and Presentation Guidelines

OVERVIEW

The Publications and Presentations Committee (P&P) serves an advisory role to the LABS Steering Committee. The primary goals of the P&P are to

1.) Promote timely, scientifically accurate, and high-quality presentation and publication of the LABS core database and individual substudies.
2.) Support broad and equitable participation by LABS investigators in presentations and publications.
3.) Define equitable rules and guidelines for authorship.
4.) Review topics, set priorities, and monitor the progress of publications and presentations through editorial support and review.
5.) Defend the academic freedom of LABS investigators to publish collective results emanating from the LABS study while providing limitations on publication of results from any one center that could threaten the integrity of the collective data.

The P&P will provide guidance relative to reporting study data. This includes assuring expert input to assure that reports meet a high standard of scientific quality, responsible conclusions, sound interpretations, and fulfillment of the overall study objectives. The committee responsibilities will primarily focus on publications policy issues during the early part of the study and then on actual publication issues during the latter part of the study. Specific responsibilities are:

1.) Recommend to the Steering Committee when particular data, whether from the Core database or individual sub-studies, can be released.
2.) Review data analysis plans and release of results.
3.) Facilitate development of study reports, presentations, and publications by defining specific types of manuscripts, setting priorities, defining timelines and overseeing writing group progress, conducting reviews and forwarding recommendations to writing groups.

The scientific integrity of LABS requires that all protocol-mandated data from sites be combined for analysis and reported as such. An individual site is permitted to report or publish data collected from its site related to bariatric surgery independent of LABS, unless it overlaps with data that will be reported or published by LABS in aggregate with other sites. This applies specifically to LABS-2 and LABS-3. LABS-1 data (30 day outcome, demographics) may be used by individual sites as required to complement site specific clinical studies which would include:

1.) Pre-existing studies/protocols for which study recruitment has been initiated before LABS patient enrollment
2.) Data routinely reported by departments of surgery for quality control such as local mortality and morbidity rates, lengths of stay, readmission within 30 days, and re-operations.

LABS investigators advocate the honor system regarding publication of studies that are similar to fundamental goals of LABS. All LABS investigators agree to avoid publishing studies or data (including non-LABS data) that may preempt publication of similar data by the LABS consortium. Thus, sites will not be required to have study protocols or manuscripts approved by the P&P prior to beginning the study or prior to publication. A site is expected to have their studies and manuscripts approved by the P&P should it have concern of possible overlap. If a site is found to violate the spirit of this system, then that site will be required to have each study and publication approved by the P&P.

A. SCOPE OF GUIDELINES

1. These guidelines apply to all of the following items that include data collected as part of the LABS consortium:
   - Original manuscripts (including validation, laboratory approaches)
   - Abstracts
   - Oral and poster presentations
   - Letters to the editor
   - Meeting proceedings
   - Extended abstracts
   - Reviews that include LABS consortium data
   - Methodology papers derived from work done in the context of LABS
   - Press releases and interviews

2. These policies apply to all results of the LABS consortium including from the core database and short- and long-term sub-studies. These policies cover all LABS or LABS-related activities including communications from ancillary studies.

3. All data derived from the LABS consortium or from specimens collected during the LABS consortium are the collective intellectual property of the study investigators, not those of any individual investigator, collaborating investigator or study sponsors from either government or industry.

4. The following types of data requests and publications do NOT fall within the scope of the P&P guidelines:
   - Requests for data providing background information (e.g., for grant proposals, for information needed to assure study operation, for progress reports).
   - Papers and abstracts that do not involve data or specimens from LABS. These papers may include data from cell lines or other patient samples except those provided by the LABS study or other NIDDK investigators for the purpose of comparing to LABS participants. If partial support for this exempt study came from NIDDK, then abstracts and papers emanating from the study are to be filed with the LABS Data Coordinating Center and the support shall be acknowledged.
   - Local presentations and accompanying syllabus material (medical school lectures, continuing education courses, grand rounds lectures, research seminars, etc.).

5. Investigators should consult the P&P chair to determine whether a data request falls into its scope, especially when questions arise about the propriety of a local presentation. If the chair cannot address such questions readily, the issue will be considered by the entire P&P via conference call or written communication.
B. PUBLICATIONS AND PRESENTATIONS COMMITTEE

1. The P&P will consist of one or two representatives from each clinical center, the Coordinating Center, and the NIDDK. Sites with two representatives receive a single vote. Although efforts will be made to schedule calls and meetings to accommodate all members, representation from the maximum number of study sites and the NIDDK takes precedence over full representation from individual sites.

2. The Chairperson will be selected by the Executive Committee. The number of consecutive or interrupted terms that a chairperson may serve will not be limited. Members of the P&P can be replaced by request of the site Principal Investigator or NIDDK Project Coordinator and a majority vote approving the replacement by the Executive Committee.

3. The P&P will mediate and settle all disputes and conflicts over publications issues, priorities, authorship and any other issues related to publications or presentations among study investigators. Investigators who perceive inequities in authorship or other problems relating to authorship should discuss these concerns with the P&P chair; if the difficulty cannot be settled in this informal manner, the concerned investigator should submit a letter to the P&P chair outlining the problem. The document will be reviewed and discussed by the P&P, and a formal written reply will be made to the investigator. If the chairperson of the P&P has a perceived or real conflict of interest with the issue, another member of the P&P will assume the chairperson’s role to resolve the dispute. If P&P deliberations fail to resolve such a dispute, the dispute will be submitted for resolution to the full Steering Committee, excepting those with a perceived or real conflict of interest.

4. The P&P reserves the right to amend P&P Guidelines as necessary.

C. TYPES OF PUBLICATIONS

1. **Main reports** are based on data from the Core database and all sub-studies. They will be designated Main-Core and Main-Substudy. These report the study design and key baseline and outcome data, as defined in the Core database and sub-study protocols, respectively.
   - **Main reports (Core)**
     - Will have authorship of the writing group and “The LABS Consortium Group.”
     - The Writing Group will include at least one investigator from each Clinical Center, Coordinating Center, and the NIDDK. Depending on the report, appropriate authors from central facilities will be included. Because so many personnel from each Center are participating in the LABS consortium, including more personnel on the writing group is impractical, yet all centers need to be represented on, and contribute to, the Writing Group. All study personnel will be listed alphabetically within center in an appendix that identifies study centers and the roles of participants at each center.
   - **Main reports (Substudy)**
     - Will have authorship “The LABS Consortium (Name of Substudy) Substudy Group”. An appendix listing all investigators participating in the substudy will be included and a footnote indicating the individuals on the Writing Group without delineating order of contribution will be given.

2. **Secondary reports** address issues more peripheral than the main study outcomes, but utilize data collected as part of LABS. This includes reports from ancillary studies that include information, or use bio-specimens, collected as part of the LABS consortium.
   - **Secondary and methodology reports (Ancillary Studies)** - The Ancillary Study Principal Investigator will nominate the Writing Group to the P&P, including the order of authorship.
The P&P may nominate other members to the Writing Group as it considers appropriate. All publications from ancillary studies will acknowledge the LABS Consortium.

Secondary and methodology reports (Other) - The individual proposing the approved report will nominate the Writing Group to the P&P, including the order of authorship. The P&P may nominate other members to the Writing Group as it considers appropriate.

3. Local reports of data collected from one or more clinical sites that are not considered to be main or secondary.

4. Abstracts, meeting proceedings, extended abstracts, oral and poster presentations.

5. Letters to the Editor.

6. Press Releases and interviews.

D. AUTHORSHIP


Primary Criteria - Participation in conception and design, analysis and interpretation of data, drafting the manuscript, critical revision of the manuscript relating to important intellectual content, and final approval of the manuscript should be included as authors.

Additional Criteria - Statistical expertise, surgical, neuropsychological, laboratory or pathology expertise that relate directly to the conduct of the study are additional criteria for authorship.

Criteria for Further Consideration – Individuals meeting any of these criteria do not necessarily merit authorship but should be considered on a case-by-case basis:

- provision of study material or patients
- data collection and assembly
- administrative, technical, or logistic support
- obtaining funding.

2. Writing Groups - The writing of manuscripts will be assigned to a Writing Group consisting of LABS consortium investigators, one of whom will be designated the Chairperson or Responsible Author. Writing Groups will be formed based on the provisions outlined in Section C.

3. All manuscripts and abstracts will include “the LABS Consortium” with or without a substudy name in the list of authors.

4. The Writing Group, plus any other contributors who fulfill criteria for authorship, will be included as authors. For journals that limit the number of masthead authors, the task of designating a smaller number of masthead authors will fall to the Steering Committee. In case this contingency arises, the following order of authorship will apply until the journal’s limit is reached:

   a. The Writing Group.
   b. Investigators identified by the Writing Group as fulfilling the criteria listed in D.1.
   c. If the journal’s limit of authors is reached, all others in the Writing Group for each publication will be listed in an Acknowledgments section of the manuscript.

5. Unless he or she delegates otherwise, the Chairperson of the Writing Group will be the first author.

6. Order of Authorship: For some manuscripts, the contribution of primary investigators may be equivalent. For others, especially secondary manuscripts, manuscripts describing ancillary studies, secondary LABS studies or methodology level of input will be considered in order of authorship. The Chairperson of the Writing Group will propose authorship order to the P&P members. The P&P may amend the order of authorship to recognize an exceptional contribution to the study or the manuscript by an individual. Upon P&P approval, the order will be submitted to the Steering Committee for final approval. For all manuscripts, factors to be included in decisions about order of authorship are contribution to concept, design, and analysis; role in...
drafting the article or revising it critically for important intellectual content; completeness and integrity of the data and specimens from the investigator's site; and leadership role.

7. The P&P will ensure that the tasks of writing and the recognition of authorship are distributed fairly among study investigators.

8. If a Writing Group does not complete its work or fails to meet timeline milestones, the P&P Committee may reassign the roles of first author or select new Writing Group members. This exigency will be exercised in the following instances:
   - if no draft is produced within 3 months of the availability of a clean data set
   - if a reviewed manuscript is not revised and resubmitted for P&P or Steering Committee review within three months
In both instances, the first author and/or Writing Group members will be given a one-month notification prior to the deadline.

9. If any Investigator terminates his or her role in LABS, the replacement will assume the original investigators’ authorship, though not necessarily leadership, role(s). For some studies in which the former Investigator may have played a primary or very strategic role, the P&P may recommend to the Steering Committee to include the former Investigator as an author (or Writing Group member). The P&P would entertain a petition from the former Investigator to be included as an author. If the former Investigator's petition is denied by the P&P, the Investigator may appeal the decision to the Steering Committee. If P&P deliberations cannot resolve an authorship dispute of a former Investigator, the issue will be decided by the Steering Committee.

10. Honorary authorship will not be considered.

E. SELECTION OF TOPICS

1. The P&P may suggest manuscript topics which will be discussed during P&P meetings and calls.

2. Any Steering Committee member may propose a topic for an abstract or manuscript. Non-Steering Committee LABS personnel may channel their requests through a Steering Committee member from their site.

3. Working group members not affiliated with a clinical center, the Coordinating Center, or the NIDDK can propose a topic through any Steering Committee member.

4. Investigators should contact the Coordinating Center to discuss study design, data, and analytical issues before submitting a proposal.

5. To form a writing group, investigators should submit the “Concept Proposal Submission Form” (Appendix A.1) to the DCC. The completed form will include:
   a. a brief description of the background/hypothesis/purpose
   b. a definition of the subjects to be included
   c. a list of variables of interest
   d. a list of possible collaborators
   e. for abstracts, the date of submission and date of the meeting
   f. for manuscripts, possible journals or books for submission

6. Incomplete forms will be returned to the investigator.

7. The Coordinating Center will arrange a conference call with the investigators to eliminate overlap or consolidate proposals with a similar topic. Alternatively, the P&P will make these determinations.

F. Approval of Topics

2 working days after receipt of “Concept Proposal Submission Form” : Coordinating Center will distribute form to P&P.

5 working days - the P&P members will fill out the “P&P Review Form” (Appendix A.2) to accept, conditionally accept (i.e., if suggested modifications are made), or deny the proposed topic. Any comments they submit will be returned to the initiating investigator. Rationale for denying the
proposal must be provided. At least four votes must be received in order for the chair to make a recommendation. If four votes are not received for a proposal within 5 working days, a voting reminder will be sent to committee members who did not vote.

P&P criteria for judging proposals:

a. scientific merit of the hypothesis or aim of the proposal
b. availability of appropriate data to address the hypothesis or aim
c. overlap with previously approved topics

**After the P&P Vote** (If a vote is other than unanimous, the P&P Chair will schedule a committee call within 3 working days)

**2 working days after receipt of vote** - The P&P chair will notify the applicant of the decision.

Upon notifying an applicant of proposal approval, the Coordinating Center will distribute a copy of the proposal to the Steering Committee and post it on the LABS website.

**5 working days of acceptance** - Steering Committee members will send additional writing group nominations to the P&P chair. The P&P chair will select the writing group from proposed investigators and designate a chair. Usually, the chair will be the person who proposed the project. As is the case for Main Reports, the selection of Writing Groups and their Chairpersons will be submitted to the Steering Committee for final approval.

**G. RESPONSIBILITIES OF THE WRITING GROUPS**

1. Following acceptance of a proposal, the Writing Group will submit a full proposal to the Coordinating Center which must include the following:
   a. the basic analytic approach
   b. mock tables to include which variables are involved at each stage and in what combination
   c. for multivariable analysis, the description of the model, including dependent and independent variables
   d. the graphic needs of the final manuscript
   e. target audience and potential journal or book
   f. proposed timeline for each stage of the analysis and writing
   g. plans for working with the statisticians at the Coordinating Center

2. All data analysis will be done through the Coordinating Center which will evaluate requests for the items listed above (G.1. a-d, g). The Coordinating Center will review the requests and provide an estimate of the time and resources required for G.1.f. The Writing Group will include the Coordinating Center’s preliminary time-and-resource estimate in the full proposal (G.1.f).

3. The Writing Group chair will assign tasks to Writing Group members and oversee completion of these tasks on schedule. Writing Group members should participate actively in writing and reviewing the manuscript.

4. If, during the course of work on a manuscript, the analysis is found to be too broad for a single manuscript, the Writing Group may suggest that the data would be more suitable for more than a single manuscript. The Writing Group must notify the P&P that they plan to narrow the scope of the manuscript, or they can submit a new written plan to the P&P for other potential manuscripts. An amended analysis plan must be submitted to the P&P if the analysis evolves or deviates substantially from that in the original plan filed with the P&P.

5. Manuscripts will be prepared at the center of the Writing Group Chairperson, with assistance from the Coordinating Center. Members of the P&P will review the completed manuscript.

6. The Writing Group Chair will submit the finalized draft of the manuscript to the DCC for P&P Subcommittee review (section I. 1-3). The Writing Group Chair will simultaneously submit the “Checklist for LABS Manuscript Submission” (Appendix A.3).
H. ADMINISTRATIVE DETAILS
1. The Coordinating Center will record topics for all manuscripts, presentations, abstracts, letters to
the editor, and any other written report of LABS data, whether from the Core database or a sub-
study.
2. All P&P forms will be available at the LABS research web site under “Publications &
Presentation.”
3. All LABS consortium manuscripts must include an acknowledgment of NIDDK funding, with
specific contract numbers, as well as NIH funding numbers of participating General Clinical
Research Centers. When appropriate, other institute, center, or commercial support is to be
acknowledged. For abstracts, acknowledgments can be limited to NIDDK (and other institute,
center, or commercial, if appropriate) funding without contract numbers, which would be too
numerous to list.
4. Requests for reprints of Main Reports and other study-wide manuscripts should be addressed to
the Coordinating Center. Reprints for local papers can be distributed either by the CC or the first
author, at the first author’s discretion.

I. EDITORIAL FUNCTIONS
1. The P&P Committee will serve as the editorial review committee for all manuscripts and abstracts.
Two P&P members, or outside reviewers with appropriate expertise, selected by the P&P chair
will be designated to provide a review of the manuscript within 10 working days for editorial
clarity and data integrity before the manuscript is submitted for publication. Reviewers of
abstracts will be allowed 5 working days to complete their review. Reviewers cannot be members
of the Writing Group. Reviewers will fill out the standardized “LABS Internal Manuscript
Review” or “LABS P&P Review – Concepts Sheets or Abstracts” forms (see Appendix A.2 &
A.4).
2. The P&P may suggest modifications before final approval or may suggest alternative journals.
3. If a dispute occurs between the authors and the P&P, resolution of the dispute is the responsibility
of the Steering Committee.

J. ABSTRACTS
1. New abstracts are to be submitted to the Coordinating Center for distribution to the P&P at least
35 working days prior to the submission deadline. The editorial process for abstract approval
will follow the process described in Section F. Priority for data analysis will be given to abstracts
by the P&P in consultation with the Coordinating Center. An abstract with a previously approved
topic may begin with J.2.
2. Prior to submission, finalized abstracts will be reviewed by two P&P members who have not
written the paper or two outside reviewers in the area of expertise will be designated to provide a
review within 10 working days of the submission deadline. Finalized abstracts and presentations
should be sent via the Abstract Submission Form (Appendix A.5).
3. Prior to the meeting or presentation itself, slide material (including tables and graphs) to be
presented for accepted abstracts and posters must be sent to the DCC at least 10 working days
prior to presentation.
4. LABS consortium data presented at local, national and international meetings must be approved
in the same way as abstracts. This may entail review of slides and printed material by the same
mechanism as that used to review abstracts. P&P approval is not required for local presentations
and accompanying syllabus material (medical school lectures, continuing education courses,
grand rounds lectures, research seminars, etc.). Investigators are encouraged to consult the P&P
chairperson when questions about the propriety of a local presentation arise. If the chairperson
cannot address such questions readily, the issue will be considered by the entire P&P (via
conference call or written communication).
5. Letters to the Editor and press releases are to be approved according to the same process as that used for abstracts.

K. PUBLICATION PRIORITIES AND ACCESS

1. No investigator may jeopardize the publication of LABS consortium data in a peer-reviewed journal by releasing or presenting data prematurely. Press releases are to be timed to coincide with publication of manuscripts and must respect any applicable publication embargoes and must be approved by the P&P and Steering Committee.

2. All manuscripts and abstracts will be stored electronically on the LABS consortium secure website, to which all study personnel have access. Slide material prepared for presentations should be made available to other LABS investigators in electronic format, and will also be stored on the LABS consortium secure website.

Acknowledgments

In drafting these publications guidelines for LABS consortium, we had the benefit of referring to publications guidelines from the following sources: authorship guidelines of the Annals of Internal Medicine and publications guidelines of the NIDDK-sponsored Virahep-C Study, HALT-C Trial, NASH consortium, and the Look AHEAD trial.