

## **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, on behalf of the Steering Committee, are to

- 1.) Promote timely, scientifically accurate, and high-quality presentation and publication of the LABS core database and substudies.
- 2.) Support broad and equitable participation by LABS investigators in presentations and publications.
- 3.) Define 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 to the Steering Committee relative to reporting study data. This includes obtaining expert input to assure that reports meet a high standard of scientific quality, responsible conclusions, sound interpretations, and fulfillment of the overall study objectives. 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 was 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 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 (DCC) 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 Data 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 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 and Steering Committee reserve the right to amend P&P Guidelines as necessary.

## C. TYPES OF PUBLICATIONS

1. **Main reports** are based on the core data from the main study (LABS-1, LABS-2) database. These report the study design or key baseline and outcome data, as defined in the study protocols. Such papers will have authorship representation from all sites. In their review of concept sheets, the P and P will provide recommendations to the Steering Committee concerning whether a concept qualifies as a main report.

### Authorship:

- Writing Group chair will be first author, followed by the writing group in alphabetical order and "The LABS Consortium Group."
  - Writing Group composition:
    - Study PIs (Clinical Center, DCC), the NIDDK), plus up to one additional investigator per site.
    - If applicable, appropriate authors from central facilities.
    - All study personnel will be listed alphabetically by center in the Study Acknowledgements.
2. **Main reports (LABS-3: Psychosocial and Diabetes)**
    - Will have authorship of the writing group and "The LABS Consortium (Name of Substudy) Substudy Group".
      - Substudy Acknowledgements listing all personnel participating in the substudy.
    - The Writing Group composition:
      - At least one investigator from each participating Clinical Center, DCC, and the NIDDK.
      - If applicable, appropriate authors from central facilities will be included.

3. **Secondary reports** address issues more peripheral than the main reports, but utilize data collected as part of LABS. All sites will be given the opportunity to participate in secondary reports. However, a site may choose to opt-out of a secondary report if there is no interest in the topic at their site.

**Authorship:**

- Writing group members who meet criteria in section D.2 below.
- All study personnel will be listed alphabetically by center in the Study Acknowledgements

4. **Ancillary Reports:** The Ancillary Study Principal Investigator will submit to the P&P the writing group including the order of authorship. If appropriate, the P&P or Steering Committee may nominate other members to the writing group.
5. **Local reports** of data collected from one or more clinical sites that are not considered to be main or secondary.
6. Abstracts, meeting proceedings, extended abstracts, oral and poster presentations.
7. Letters to the Editor.
8. Press Releases and interviews.

**D. AUTHORSHIP**

1. After a concept sheet is approved, the DCC will solicit writing group participation from LABS PIs by a certain date PIs must respond in the allotted time; a lack of response will be considered to indicate no nominations. Writing group members cannot be added after an abstract or manuscript is well underway without agreement of the writing group chair, or as described in section D.6 below..
2. Authors must participate in the writing of the paper according to guidelines of the International Committee of Medical Journals. Critical issues include that authors;
  - Make “substantial contributions” to “conception and design, or data acquisition, or analysis and interpretation of data” AND
  - Participate in drafting the manuscript or critical revision with respect to important intellectual content, AND
  - Provide final approval of the manuscript.

**Additional Criteria** -Statistical expertise; surgical, neuropsychological, laboratory or pathology expertise; administrative, technical or logistic support that relate directly to the conduct of the study are additional criteria that may fulfill the first “substantial contribution” criterion above.
3. The Writing Group members who meet criteria, 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 members who fulfill criteria listed in D.1.
  - b. Others 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 meeting authorship criteria will be listed in an Acknowledgments section of the manuscript.
4. Timeliness of participation: Writing group members’ participation will be monitored regarding level and timing of participation in the manuscript-writing process. The expected turn-around time for writing group review of a draft will be two weeks. Writing Group members must inform writing group chairs if they cannot meet the deadline and request an extension or withdrawal from the writing group. Writing Group members who fail to meet deadlines may be removed as authors. Should a writing group chair consider removing a writing group member due to lack of participation as required by Section D.2 above, the writing group member will be notified by the writing group chair, with rationale provided, and their local PI will be copied on the notification.

After the notification, failure to comply with writing group responsibilities may result in immediate removal from the writing group, at the writing group chair's discretion.

5. Order of Authorship: With the exception of Main reports, for which order is specified in section C.1 above, the Chairperson of the Writing Group will propose authorship order. Either the P&P or the Steering Committee may amend the order of authorship. 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. Alphabetical order of co-authors is permissible.
6. If a Writing Group does not complete its work or fails to meet timeline milestones, the P&P Committee may recommend to the Steering Committee reassigning the roles of first author or selecting new Writing Group members. This exigency may 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 3 months

In both instances, the Writing Group chair and Writing Group members will be given a one-month notification prior to the deadline.
7. If any Investigator terminates his or her role in LABS, the replacement may 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 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.
8. 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. Steering Committee members may propose a topic for an abstract or manuscript by submitting a "Concept Proposal Submissions Form" to the study coordinator at the DCC. Non-Steering Committee LABS personnel or work group members not affiliated with a LABS site may channel their requests through a Steering Committee member.
3. Investigators are encouraged to contact the DCC to discuss study design, data, and analytical issues before submitting a concept sheet.
4. To form a writing group, investigators should submit the "Concept Proposal Submission Form" (Appendix A.1) to the Project Coordinator at 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
5. Incomplete forms will be returned to the investigator.
6. The DCC 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. P&P Communication**

1. The P&P will regularly have telephone conference calls to discuss concept sheets/abstracts/manuscripts, and discuss other business in the P&P's purview.
2. All proposals received on or before the 15<sup>th</sup> of a calendar month will be reviewed on that month's P&P call. Proposals received after that date will be held for discussion on the next month's call. During the call, the P&P members will vote on the topics as:
  - a. Accept
  - b. Provisional Acceptance (accept, but with comments that need to be addressed in a revised concept sheet)
  - c. Reject: Reasons for rejection will need to be provided.
3. If a P&P committee member cannot make the monthly call, his or her vote may be sent to the Project Coordinator at the DCC via the standard P&P Review Form (Appendix A.2).
4. At least four votes must be received for the chair to make a recommendation.  
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
5. Following the call, the minutes and corresponding concept sheets will be distributed to the Steering Committee for review. The Steering Committee will be given 5 working days to respond with any objections and, if appropriate, nominate writing group members.
6. The applicant will be notified of the decision after the Steering Committee vote.

## **G. WRITING GROUPS**

1. Following acceptance of a proposal, the Writing Group will submit a full proposal to the DCC 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 meeting, journal book, or other means of dissemination
  - f. proposed timeline
  - g. plans for working with the statisticians at the DCC
2. All data analysis will be done through the DCC which will evaluate requests for the items listed above (G.1. a-d, g). The DCC will review the requests and provide an estimate of the time and resources required for G.1.f. The Writing Group will include the DCC'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.
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 DCC.
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).
7. The Steering Committee will have final approval on the writing group members.

## H. ADMINISTRATIVE DETAILS

1. The DCC will record topics for all manuscripts, presentations, abstracts, letters to the editor, and any other written report of LABS data.
2. All P&P forms will be available at the LABS research web site under “Publications & Presentation.”
3. All LABS consortium manuscripts must include the standard LABS Acknowledgments. 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.

## I. EDITORIAL FUNCTIONS

1. Two P&P members, or outside reviewers with appropriate expertise, selected by the P&P chair will be designated to provide a review of manuscripts within 10 working days for editorial clarity and data integrity before the manuscript is submitted for publication. Reviewers will fill out the standardized “LABS Internal Manuscript Review” form (see Appendix A.3). The Steering Committee retains final authority to submit manuscripts.
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

Abstracts for an approved topic:

1. Will be reviewed on a P&P call and subsequently by the Steering Committee. For major scientific meetings (The Obesity Society, ASMBS, etc) for which there may be a number of LABS abstracts, a special call will be scheduled to review the abstracts 2 weeks prior to the deadline. Deadlines and reminders for such calls will be sent to all study personnel at least 2 months prior to the submission deadlines.
2. If an abstract is accepted, slide material (including tables and graphs) to be presented for accepted abstracts and posters must be sent to the DCC to distribute for Steering Committee review **at least 10 working days prior to presentation.**
3. After presentation, final materials must be submitted to the DCC to be posted on the study web site. Study personnel may use these materials. As with the standard slide set, the study coordinator with must be informed of what, where, and when they are presenting to maintain a complete accounting of publications and presentations utilizing LABS data.

## K. Expedited Process for Ancillary Papers/Reports

1. Ancillary Investigators wanting to submit a manuscript/abstract should follow the guidelines for new topics in Section F.
2. A draft of the manuscript/abstract should be sent to the DCC for Steering Committee review to ensure that the publication/presentation does not overlap with a LABS topic or pre-emptively report data from the LABS consortium data.

## L. 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.

**Appendix A.1**  
**Concept Proposal Submission Form**

This form is used to propose a new writing group. Please submit completed forms via e-mail to the DCC Study Coordinator ([labs@edc.pitt.edu](mailto:labs@edc.pitt.edu)) or fax to (412)383-5841(ATTN: LABS).

**Submission Date (mm/dd/yyyy):**

**Working Title:**

**Individual Submitting Proposal:**

**Recommended Writing Group Chair (if different from submitter):**

**Possible Collaborators/Co-authors:**

**Brief Description (topic background/hypothesis/purpose):**

**Analysis**

**Overall Strategy:**

**LABS data points to be used:**

**LABS subjects to be included:**

**Keywords:**

**Possible journals:**

**Possible meetings (if available, indicate abstract submission deadline):**

*Estimated Timeline:*

Draft to Writing Group (mm/yyyy):

Final Draft approved by Writing Group (mm/yyyy):

Submit Checklist & Manuscript to P&P (mm/yyyy):

Submit to Journal (mm/yyyy):

Additional Comments/Notes

**Appendix A.2**  
**P&P Review Form – Concept Sheets or Abstracts**

Submit completed forms via e-mail to the DCC Study Coordinator ([labs@edc.pitt.edu](mailto:labs@edc.pitt.edu)) or fax to (412)383-5841 (ATTN: LABS).

**Title:**

**Lead Author:**

**Reviewer:**

**Type of Report: (Main / Secondary )**

**Brief Summary:**

**P&P Checks:**

- a. Hypothesis clearly stated?
- b. Variables & sample defined?
- c. Analytic strategy outlined?
- d. Any overlap issues?

**Major Comments:**

**Minor Suggestions:**

**Recommendation:**

Not Approved

Conditional Approval – Major Revisions Needed, Resubmit to P&P

Conditional Approval – Minor Revisions Needed, Resubmit to P&P chair only

Approval

**Appendix A.3**

**LABS Internal Manuscript Review**

Submit completed forms via e-mail to the DCC Study Coordinator ([labs@edc.pitt.edu](mailto:labs@edc.pitt.edu)) or fax to (412)383-5841(ATTN: LABS).

**Title:**

**Writing Group Chair:**

**Reviewer:**

**Date:**

**Brief Summary:**

**P & P Checks:**

- |   |                                  |                                 |
|---|----------------------------------|---------------------------------|
| a. Analytic review needed?  | Yes [ <input type="checkbox"/> ] | No [ <input type="checkbox"/> ] |
| b. Manuscript generally corresponds to approved proposal and analytic plan? | Yes [ <input type="checkbox"/> ] | No [ <input type="checkbox"/> ] |
| c. Any overlap issues resolved?   | Yes [ <input type="checkbox"/> ] | No [ <input type="checkbox"/> ] |
| d. LABS appropriately credited?   | Yes [ <input type="checkbox"/> ] | No [ <input type="checkbox"/> ] |
| e. LABS standard terminology used?  | Yes [ <input type="checkbox"/> ] | No [ <input type="checkbox"/> ] |

**Major Comments:**

**Minor Suggestions:**

**Recommendation:**

- [  ] Not Approved
- [  ] Conditional Approval – Major Revisions Needed, Resubmit to P&P
- [  ] Conditional Approval – Minor Revisions Needed, Resubmit to P&P chair only
- [  ] Approval

## **Appendix A.4** **Abstract Submission Form**

This form is used to submit an abstract for a scientific meeting. Please submit completed forms via e-mail to the DCC Study Coordinator ([labs@edc.pitt.edu](mailto:labs@edc.pitt.edu)) or fax to (412)383-5841 (ATTN: LABS).

**Submission Date (mm/dd/yyyy):**

**Working Title:**

**Individual Submitting Abstract:**

**Is this abstract related to an existing Writing Group? Yes / No**

**If yes, which Writing Group?**

**If not, will a Writing Group be formed for later submission of a concept proposal for a manuscript? Yes / No**

**Has this abstract been presented before? Yes / No**

**If yes, when (mm/dd/yyyy):**

**Where:**

**Lead Author (if different from submitter):**

**Possible Co-authors:**

**Name of meeting to which abstract will be submitted:**

**Date and Location of meeting:**

**Abstract submission deadline (mm/dd/yyyy):**

**Form of presentation:**  Oral  Poster  Unknown

**Keywords:**

**Abstract (Please type the text of your abstract here):**

*For DCC Use Only:*

DCC Analyst:

Keywords:

Timeline:

Final Draft approved by P&P reviewers (mm/yyyy):

Submit to Meeting (mm/yyyy):

Additional Comments/Notes