

Teen-LABS Consortium Publications and Presentations Guidelines

Version 3.0

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Teen-LABS Consortium Publications and Presentations Guidelines

The following is the formal policy for presenting and publishing Teen-LABS data, including preparation of manuscripts, assigning tasks in analysis and writing, writing group membership, authorship, internal review, and other issues related to abstracts, presentations, and publications. The policy covers full manuscripts, abstracts, and other publications and presentations. The process will ensure that study results are disseminated in a timely, accurate, and clear manner. The Teen-LABS Publications and Presentations Committee (PPC) will oversee dissemination and serves an advisory role to the Teen-LABS Steering Committee.

1.0 Publications and Presentations Committee (PPC)

1.1 Goals & Responsibilities

- To organize, lead in the development of, and promote timely, scientifically accurate, and high-quality presentation and publications from the Teen-LABS Consortium investigators.
- Support broad and equitable participation by Teen-LABS investigators in presentations and publications.
- Define equitable rules and guidelines for authorship.
- Review topics, set priorities, and monitor the progress of publications and presentations through editorial support and review.
- Defend the academic freedom of Teen-LABS investigators to publish collective results emanating from the Teen-LABS study while providing limitations on publication of results from any one center that could threaten the integrity of the collective data.
- Provide expert guidance for the reporting of study data to ensure that reports meet a high standard of scientific quality, responsible conclusions, sound interpretations, and fulfillment of the study objectives.
- Collaborate with Data Coordinating Center (DCC) to recommend to the Steering Committee when particular data can be released.
- To conduct a timely review of proposals for publications, presentations, and abstracts as well as to review data analysis plans and plans for release of such results.
- Serve as the editorial review committee for manuscripts and abstracts.
- Ensure appropriate writing group membership, and to monitor the progress of proposed manuscripts and presentations to facilitate their prompt completion and publication.
- Mediate and settle disputes and conflicts over publication issues, priorities, authorship among study investigators.
- To amend PPC Guidelines based on the needs of the Consortium.

1.2 Membership

- Membership of the PPC will be established by the Teen-LABS steering committee.
- The PPC will function as a standing committee.
- The PPC will consist of 1 (or 2 as deemed necessary based on workload) representatives from each clinical center, the DCC, and the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). Sites with 2 representatives have a single vote.
- The PPC reserves the right to include 1-2 “ad-hoc/standing” members with particular expertise in areas of interest to Teen-LABS as needed. These members would be subject matter experts to inform and advise but would not have a vote.
- Members of the PPC can be replaced by request of the site Principal Investigator or NIDDK Project Scientist and a majority vote approving the replacement by the Executive Committee.
- The Chairperson of the PPC will be selected by the Teen-LABS Executive Committee. The term of initial appointment is 5 years. The number of consecutive or interrupted terms that a Chairperson may serve will not be limited. In order to ensure fairness in the management and facilitation activities of the PPC Chairperson, the PPC Chairperson will not have a vote on the PPC, except in the case of ties. Chairperson primary responsibilities include managing the processes of proposal review and approval, and the monitoring and encouragement of progress of work through to the point of publication or presentation. This includes the following tasks and responsibilities:
 - Convening and chairing calls and in-person meetings of PPC
 - Assuring equitable access to and use of Study data
 - Overseeing progress on approved manuscripts proposals
 - Resolving conflicts
 - Developing and distributing agendas, minutes, and reports, with the support of the Teen-LABS Data Coordinating Center
 - Participating in Steering Committees meetings and updating members of PPC activities
- There will be a vice-Chairperson of PPC, proposed by the PPC and appointed by the Steering Committee. This individual will be selected from among the members of the PPC. The vice-Chairperson will facilitate meetings or conference calls and other committee processes when the Chairperson cannot perform these functions. The vice-Chairperson will be a voting member of the PPC.
- To coordinate with Study Chairperson and DCC to make decisions regarding Study payment for costs related to publications and presentations. Potentially reasonable costs that the Consortium may cover include abstract submission fees, publication fees, and poster preparation costs. No plans exist for payment for professional writing services.

1.3 PPC Meetings

- The frequency of PPC meetings will be dictated by the volume of activity the committee is overseeing; the initial frequency of meetings will be monthly, and this schedule will be

adjusted subsequently if needed to meet PPC needs. PPC meetings will be conducted by telephone or video conference call unless arranged otherwise in advance of the meeting.

- Although efforts will be made to schedule PPC calls and meetings to accommodate all members, representation from the NIDDK and the majority of study sites takes precedence over full representation from individual sites.

2.0 Teen-LABS Consortium Honor System

Teen-LABS investigators agree that data derived from the Teen-LABS Consortium or from specimens collected during the Teen-LABS Consortium are the collective intellectual property of the Consortium investigators, not that of any individual investigator, collaborating investigator or study sponsors from either government or industry. The Consortium members will have exclusive use of this intellectual property for the period that the Study is funded and for a 2-year period beyond the date of final funding. The scientific integrity of Teen-LABS will generally require that protocol-mandated data from sites be combined for analysis and reported as such.

Teen-LABS investigators agree to avoid publishing studies or data (including non-Teen-LABS data) that will preempt publication of larger studies using similar data by the Teen-LABS Consortium.

- A Consortium investigator is expected to submit proposals for publications (as defined in Section 3.3) for PPC approval if the project uses data from participants enrolled in the Consortium, requires Consortium resources such as personnel or payment of fees, or uses the name “Teen-LABS” in an official capacity.
- For publications that do not involve Consortium participants, data or other resources, site PIs should inform the PPC by completing a “Writing Group & Concept Form” (see Appendix – Form 1) and indicating on the form that the submission type is a “Non-Teen-LABS Project.” However, approval of the project by the PPC is not required. This will allow the Teen-LABS study to catalog such publications and will allow Consortium members to be aware of the planned publication.
- Projects that do not require PPC approval, but do require notification of the PPC include those that involve:
 - Pre-existing studies/protocols/data/specimens for which study recruitment was initiated and completed before Teen-LABS enrollment began at the site
 - Data routinely reported privately by departments of surgery for quality control such as local mortality and morbidity rates, lengths of stay, readmission within 30 days, and re-operations.

Teen-LABS investigators agree to abide by the policies, guidelines, and collaborative principles governing Consortium communications outlined in this document.

3.0 Scope of Publications and Presentations Guidelines

3.1 Definitions of Teen-LABS data

Teen-LABS Consortium data are any data within the core database or any approved ancillary studies that utilize any aspect of the Teen-LABS core database.

3.2 Definitions of Teen-LABS specimens

Teen-LABS Consortium specimens are any biospecimens banked at an approved NIDDK repository, obtained during protocol mandated study procedures.

3.3 Definitions of Types of Communication

Any communication from Teen-LABS and its approved ancillary studies will be classified as a publication. This includes letters and short communications, oral and poster presentations, press releases, or interviews.

Publications. A publication (also known as “paper” or “manuscript,” including abstracts) is any document submitted to a professional society or journal listed in the Index Medicus or any popular periodical with national circulation, including categories such as “short reports” and “letters” that include new data not presented elsewhere. Regardless of the category of type of publication used by a journal, any transmission that presents new information will be treated as a publication.

Letter. A letter is defined as: (1) a document submitted by a Study investigator to a professional journal reporting original Study data in a format not considered a publication (e.g., Short Communication); (2) a response to a non-Teen-LABS publication which may or may not include original Teen-LABS data; (3) a response to a letter written by non-Teen-LABS investigator in response to a Teen-LABS publication. Letters containing previously unpublished data are treated as regular publications for approval purposes, though the review may be expedited.

Presentations. A presentation is the delivery of information to scientific, professional, or public groups. A presentation may include an abstract to be published by the group to which the presentation is made, or an invited presentation using Study data. Presentations include oral and poster formats.

Press Releases. A press release is defined as a document given to radio, television, newspapers, popular periodicals, web sites or scientific journals (including publications of pharmaceutical companies or professional organizations) not indexed in Index Medicus.

Interviews. An interview is any discussion with a member of the press, a science writer, or a radio or television commentator, who in turn provides information for public dissemination.

Preliminary data in support of a new grant proposal. To maintain the integrity of the Teen-LABS data, requests for use of specific data in new grant proposals must be presented to the PPC for formal approval.

3.3 Exceptions to Scope of Teen-LABS Publications and Presentations Guidelines

The following types of data requests and publications do NOT fall within the scope of the PPC guidelines:

- Requests for data providing background information (e.g., for information needed to assure study operation, for progress reports).
- Local presentations and accompanying syllabus material (medical school lectures, continuing education courses, grand rounds lectures, research seminars, etc.) based on single site data.

- Local presentations for the purpose of study recruitment and physician information do not require PPC approval. Such local presentations will be based upon generally available results will not result in any publication. If publication from a local presentation is expected, then PPC approval using the guidelines included here is required.
- While these above-mentioned situations can be considered exempt from PPC rules, an investigator who wishes to use the PPC policy and processes may do so at their discretion, if such use is deemed beneficial.

Investigators should consult the PPC Chairperson or Study Chairperson to determine whether a data request falls into the scope of the PPC, especially when questions arise about the propriety of a local presentation. If the PPC Chairperson or Study Chairperson cannot address such questions readily, the issue will be considered by the entire PPC via conference call or written communication.

4.0 Publications

4.1 Categories of Papers

Generally, Study papers will be considered in 5 categories: *key papers, investigator-initiated papers, hybrid, other, and ancillary study papers.*

Key papers. The PPC will define as *key papers* those that represent the primary publication of the major aims of the study. This would include papers that address each of the Study's primary hypotheses, outlined in the original funded grant proposal and which appear in bold text in the Study Protocol in Sections 4.D1-4.D10. Examples of papers in this category will be descriptive papers addressing baseline cohort characteristics (anthropometric, medical, behavioral features), perioperative risks of surgery, and longer term risks of surgery, changes in major metabolic variables, comorbidities, body composition, and psychosocial outcomes of adolescent bariatric surgery.

Important Investigator-initiated papers. This category will include all other papers using primary data from the Study, used in such a way as to test secondary hypotheses of the study. These could include any studies based on primary analyses that were not specifically described in the grant or protocol, or secondary analyses of study data in conjunction with other non-study collaborative data collected by investigators or colleagues. For these projects, submission of the proposal to the PPC is required. Sub analyses involving outcomes related to the primary study questions should be presented after publication of the initial report(s) outlined above. Examples of papers in this category will be validation studies, methods papers, case reports, predictors of weight loss efficacy, hepatopathology, predictors of adherence to supplements, longitudinal healthcare utilization, etc.

"Hybrid" papers. Hybrid publications or abstracts are based on data/specimens/analyses that were not collected entirely under the Teen-LABS protocol, but include data that emanated from both 1) Teen-LABS resources (subjects, data, coordinator time, DCC staff time or analyst time, or other study infrastructure), or subjects AND 2) other Non-Teen-LABS data sources (e.g., other bariatric studies at the Consortium site(s) that pre-dates Teen-LABS). Hybrid projects will be expected to proceed with the PPC approval process and recognize the grant and Consortium's contribution.

Other papers. This category will include papers that utilize Consortium resources or data but do not fit into the above categories. Other papers could include invited topic reviews, or clinical process (non-outcomes), or site-specific papers.

Ancillary Study papers are papers based on data collected within ancillary studies that were formally approved by Teen-LABS and which also use core Teen-LABS data from the main study. All proposals for papers must be formally submitted to the PPC (see below, Section 4.5, Submission of Proposals for Manuscripts).

4.2 Organization of Topics for Papers

In order to ensure that Study papers appropriately address the scope of science available in the Study, general topic areas will be designated by the PPC that reflect the major aims and hypotheses of the study (e.g., perioperative morbidity, comorbidity change, psychosocial changes, change in physical activity and eating behavior, anthropometric and nutritional outcomes). Most designated topic areas are expected to yield more than one paper. Specific papers within a topic area may include a key paper(s) or other investigator-initiated paper. The specific topic areas will be approved by the PPC. Topic areas will serve to focus publication work of the Consortium.

5.0 Authorship

5.1 Authorship guidelines adopted by Teen-LABS

Teen-LABS authorship guidelines are based on those published by the International Committee of Medical Journal Editors (N Engl. J Med 1991; 324:424-8) and are summarized below.

- Primary Criteria for Authorship** - 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.
- Additional Criteria for Authorship** - Statistical expertise, surgical, psychological, laboratory or pathology expertise that relate directly to the conduct of the study.
- Criteria for Further Consideration** – Individuals meeting any of the following 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.

5.2 Eligibility Criteria for Authorship of Publications using Study Data

Decisions about authorship for the following categories of abstract/manuscripts using collaborative data should use the following guidelines:

General: Manuscript proposals will require a writing group (WG). The WG is ultimately responsible for the concept development and writing and publication of the manuscript. The WG will have a Chairperson who directs the project. A Co-chairperson also will be named to facilitate progress in the absence of the WG Chairperson. Co-chairpersons may be identified either by the WG Chairperson or by PPC and must be approved by PPC (See Section 9).

The authorship order for Teen-LABS publications will be determined by the WG Chairperson, based on his or her assessment of individual contribution to the WG project. In general, the WG

Chairperson or Co-chairperson will occupy the first or last authorship position, as these two individuals will take the most responsibility for that specific report, based on genesis of idea, conduct of analysis, or the actual writing of the paper. Final authorship, ordering of authors (and number of authors per site) should be based on WG membership and also take into account development of the study question, quality of the data, and participation in analysis and preparation of the manuscript.

Key papers. For Key papers, the Study Chairperson, in collaboration with the Study Co-Chairperson for Behavioral Sciences and PPC Chairperson will select the WG Chairperson and Co-chairperson. Decisions regarding WG leadership and membership for Key papers may be based in part on the scientific needs of the study and in part on proposals for publications submitted to the PPC by study investigators. Investigators at each site within the Consortium, NIH, and central laboratory will be encouraged to submit proposals for publications and to participate in WGs. The WG Chairperson is expected to invite at least one investigator from each site to join the WG. All major papers will include individual WG authors' names and "for the Teen-LABS Consortium."

In the event that the number of contributing WG members exceed that allowable by a particular publisher, authorship will be listed as the WG Chairperson and Co-chairperson "for the Teen-LABS Consortium". In this unique case, the other writing group members for such papers will be listed alphabetically in footnote or other site according to journal-specific practice.

Important Investigator-initiated papers and other papers. Investigators at each center, including the NIH and central laboratory, will be strongly encouraged to submit proposals to the PPC and then Chairperson or Co-chairperson WGs. WG Chairpersons will be encouraged to provide an opportunity for investigators across all sites involved in the Consortium. All papers in this category will include individual authors' names and "for the Teen-LABS Consortium."

Ancillary Study papers, abstracts and invited presentations. The PPC will review proposals, abstracts, manuscripts and presentations with the same degree of scientific rigor as for the key papers and important investigator-initiated papers, and will encourage opportunity for investigators across all sites involved in the ancillary. For ancillary study papers, the Study Chairperson will not have the responsibility or the authority to assign paper topics or designate chairpersons for the writing groups. Liaisons will be assigned to all papers to facilitate progress and updates. Invited presentations must be approved as an "other" paper.

Additional considerations regarding authorship. The PPC will review/approve the ordering of authors as proposed by the WG Chairperson, as needed, for all papers, abstracts, and presentations, taking into consideration the level of participation in the analysis and preparation/revisions of the manuscripts. The Teen-LABS Consortium will be acknowledged as a co-author as permitted by the policies of journals. All members of the WG who are named as authors, either in the authorship position below the title or in a footnote, will meet the criteria for authorship as specified by the International Committee of Medical Journal Editors and any additional requirements imposed by the journal. WG members who do not meet these criteria will be listed, with their permission, in the acknowledgments or in an appendix. *Manuscripts submitted to the PPC must contain a paragraph indicating the level of participation for each co-author.*

Increasingly, multicenter trials are attributed to a corporate author. All members of the group, who are named as authors, either in the authorship position below the title or in a footnote, should fully meet the above criteria for authorship. Group members who do not meet these criteria should be listed, with their permission, in the Acknowledgments or in an appendix (see Acknowledgments).

The order of authorship should be a joint decision of the co-authors on the WG. Because the order is assigned in different ways, its meaning cannot be inferred accurately unless it is stated by the authors. Authors may wish to explain the order of authorship in a footnote. In deciding on the order, authors should be aware that many journals limit the number of authors listed in the table of contents and that the US National Library of Medicine (NLM) lists in MEDLINE only the first 24 plus the last author when there are more than 25 authors.

Acknowledgements. At an appropriate place in the article (the title-page footnote or an appendix to the text; see the journal's requirements), one or more statements should specify 1) contributions that need acknowledging but do not justify authorship, such as general support by a departmental chair or members of the Adjudication committee; 2) acknowledgments of technical help; 3) acknowledgments of financial and material support, which should specify the nature of the support; and 4) relationships that may pose a conflict of interest (see Conflict of Interest). Persons who have contributed intellectually to the paper but whose contributions do not justify authorship may be named and their function or contribution described—for example, “scientific adviser,” “critical review of study proposal,” “data collection,” or “participation in clinical trial.” Such persons must have given their permission to be named. Authors are responsible for obtaining written permission from persons acknowledged by name, because readers may infer their endorsement of the data and conclusions. The Coordinating Center can assist with obtaining this information. All publications must provide contact information for the corresponding author (e.g., e-mail address, fax, telephone number). Additionally, publications “must” cite grant funding sources and numbers [e.g., “This study was conducted as a cooperative agreement and funded by the National Institutes of Diabetes and Digestive and Kidney Diseases with a grant to University of Colorado Denver and Dr. Thomas Inge (U01 DK072493 & UM1 DK072493)] and reference www.Teen-LABS.org.

Technical help. Technical help should be acknowledged in a paragraph separate from that acknowledging other contributions.

Individuals not within Consortium. Individuals who made a substantive contribution to the development of the questionnaires, data collection, or study design for Teen-LABS will be given first opportunity to explore secondary hypotheses using collaborative data. Persons who were not involved in the questionnaire development, study design, or data collection (e.g., Investigators and Fellows not previously participating in the Study) *may* be allowed to conduct analyses and write abstracts/papers using Teen-LABS data if the topic 1) was not planned as an analysis project by other Consortium members, 2) if sponsored by member of the Steering Committee, and 3) the proposed project is accepted by all members of the PPC *and* the Steering Committee prior to analysis.

Papers related to laboratory studies on secondary hypotheses conducted by laboratory investigators using collaborative data. In most cases, the responsibility and therefore the first authorship credit should belong to the person (or designee of that person) who designs and directs the analysis and writes the paper. In many cases, this will be the director of the respective laboratory group. In terms of authorship, appropriate recognition of study sites and other investigators including laboratory investigators should be given. The nature of recognition will be according to the degree to which the report relates to the study's stated objectives. The “Teen-LABS Consortium” should be acknowledged as a co-author as permitted by journal policies.

6.0 Analysis and Reporting Results based on Site-Specific Data

The following guidelines apply to analyses using site-specific (single site) data generated as part of the Study. Individual sites may use site-specific data for the purpose of evaluating quality of care within their site and/or for providing feedback of clinical data to clinicians and individual Study subjects without the permission of either the PPC or the Steering Committee. They may also use their own data in new grant applications without additional permission; however, the DCC must be notified of such use for the purpose of tracking ancillary projects. The Steering Committee must approve the inclusion of Teen-LABS Consortium data in new grant proposals.

Site-specific analyses are appropriate when an individual study site (or sites) has collected data that are unique to that study site, or are addressing a study question particularly pertinent to that site. Projects using site-specific Teen-LABS data must submit a proposal to the PPC and obtain approval by the committee. In general, the first author should be the individual who took the most responsibility for that specific report based on genesis of idea, conduct of analysis, and the actual writing of the paper. If applicable, other study sites and/or investigators should be recognized as authors. The nature of the recognition should be based on the degree to which other sites or investigators contributed to the study, and in general, the Consortium should be acknowledged. All authors should have the opportunity to review any reports on which they are listed prior to their submission for presentation or publication.

Because the Study has been designed and conducted as a multi-site collaborative study, no site-specific analyses should be done using primary study hypotheses. Furthermore, reports dealing with secondary analyses should preferentially be reported with multi-site rather than single site data. However, site-specific analyses and reports may be pursued if approved by the PPC. In addition, writing group Chairpersons may propose the exclusion of a site or sites, or subgroups of the population, if warranted by the scientific rationale of the proposed analysis and approved by the PPC.

7.0 Submission of Proposals for Publications (see appendix for all forms)

The publication process of a Study manuscript starts with the submission of a proposal to the PPC. All Teen-LABS manuscripts, abstracts, or invited presentations must follow this process. The written proposals serve to minimize overlap between papers and will follow a standard format, including a description of the hypotheses of the paper, a one- or two-page paper topic description including a list and description of variables, and the general statistical approach, as well as the list of writing group members. Abstracts and invited presentations should, with only rare exception, also lead to a published paper for Teen-LABS.

Prior to submission of a manuscript proposal, the originating author will review PPC documentation regarding papers already proposed, and will communicate directly with the Chairperson of PPC in order to avoid inappropriate overlap or inefficient use of study resources.

For key papers, the Study Chairperson/Co-chairperson and PPC Chairperson will select a WG Chairperson based on scientific needs of the Study. A WG Co-chairperson and lead Statistician will then be chosen and approved by the PPC and WG Chairperson. These individuals, along with one or two other Study investigators, including a DDC statistician or analyst, will write the proposal and submit the proposal to the PPC.

For Investigator-initiated papers, the initiating Investigator (WG Chairperson) and WG Co-chairperson along with 2 - 3 other Investigators and a DCC Statistician/analyst, will write the proposal and submit the proposal to the PPC.

The publication proposal will provide basic administrative information (e.g., study title, format, writing group membership, statistician, external submission deadlines) and a broad description of the intended paper (e.g., lay language summary, background, specific aims/hypothesis, design/methods, data analysis plan, and power/sample size determination).

7.1 Teen-LABS Duality of Interest Disclosure Policy

Duality of Interest Disclosure Policy: Disclosure of financial relationships with companies or other entities that have interests or relevance to Teen-LABS research or activities.

The purpose of the policy is:

- To avoid potential bias and susceptibility to influence from pharmaceutical, biotechnology, and medical device manufacturers or other entities whose products or services could or will be used in management or care of participants in Teen-LABS, or whose products or services would be directly and predictably affected in a major way by the results of Teen-LABS studies.
- To avoid the appearance of bias or susceptibility.

Disclosure procedure: Statement of relationships with pharmaceutical and medical device manufacturers or other entities whose products or services are used in management or care of Teen-LABS participants or predictably affected by results of the Teen-LABS project will be completed.

In general, relationships with a combined level of interest to the investigator, spouse, and dependent children must be disclosed in the following categories:

- No interest
- \$15,000 or less or 5% equity or less
- More than \$15,000 or more than 5% equity

Initial duality of interest disclosure statements are to be updated **annually**, and will be collected by the DCC or other body appointed by the SC.

Review procedure: Statements will be summarized by the DCC, reviewed by NIDDK and the Executive Committee, and will be kept on file at the DCC.

Who must sign a duality of interest disclosure statement:

- Principal investigators
- Co-investigators
- Voting members of the SC
- DSMB members
- Members of standing committees
- Advisors or consultants for Teen-LABS

Examples of interests in any company or entity that meets criteria stated in “Purpose” section above that must be disclosed:

- Ownership of stock, equity, or other financial interest
- Employment, office, or directorship
- Personal compensation
- Consulting or advisory arrangements
- Grants, contracts, research, training, or other support.
- Travel grants to educational symposia
- Intellectual property rights
- Other relationships in which there is or seems to be a dependency relationship
- Relationship with a company or other entity that may affect academic advancement or status, such as sponsorship of an endowed chair or establishment of a fund for use by the Teen-LABS investigator

Study duration to which policy applies:

- For the duration of Teen-LABS funding or activity and, beyond that, for up to two years or until all major publications are completed.

Possible consequences of a relationship judged to be a conflict of interest with Teen- LABS:

- No action; disclosure alone is sufficient
- Relationship is described in a footnote to a paper
- Investigator is banned from authorship of 1 or more papers (depends on relationship of conflict to content of paper)
- Investigators may not vote on any issue related to a company or other entity with which they have a relationship, regardless of the monetary value or nature of the relationship; however, voting rights on such issues may be delegated to a co-investigator, as long as the co-investigator has no relationship with the company or entity

8.0 Manuscript Proposal Review Process within PPC

8.1 Goals of PPC Review

- To ascertain that the formal manuscript proposal format has been followed.
- To determine that a clear and accurate analysis plan is included in the proposal.
- To determine if there is inappropriate overlap between the proposed manuscript and any other papers proposed or in progress. In such cases, the investigator will be encouraged to collaborate on the existing proposal/manuscript if appropriate.
- To confirm that each site has had a reasonable opportunity to participate and that the proposed writing group is appropriate. The PPC may solicit additional members of the Consortium to participate in any WG.

- To assign a Liaison from among the PPC members (excluding any PPC member who also may be a writing group member). The assigned PPC Liaison is the person through whom communications will occur regarding the manuscript.

8.2 Process for PPC Approval of Proposal

PPC Step 1. Scheduling Review of Proposals. The PPC members will be given adequate time for review of each proposal. Therefore, proposals must be submitted to the DCC a minimum of 10 business days prior to a scheduled PPC meeting for the proposal to be considered. The PPC Chairperson and Committee as a whole reserve the right to defer discussion of a proposal if the upcoming agenda is full, or if it is obvious that the proposal will require further work prior to a productive discussion. The WG Chairperson will be notified accordingly of when the proposal will be discussed by the full PPC.

PPC Step 2. Review of Proposals. The WG Chairperson will be notified of the time of the PPC meeting and asked to be available by telephone for questions if needed. If the WG Chairperson is not available, s/he should ask the Vice-chairperson to participate in the PPC call.

PPC Step 3. Consideration of Priority. The PPC has the authority and responsibility to rank the priority of abstracts and papers for analysis. This will be done in consultation as needed with the Steering Committee, and the WG Chairpersons of specific papers, as well as the DCC to take into account issues related to work load and efficiency.

PPC Step 4. Actions on Proposals. Each member of the PPC, except the PPC Chairperson, will have one vote in the decision about a paper proposal. If a PPC member is the WG Chairperson, he or she will be recused from the vote. In the case of a tie vote, the PPC Chairperson will cast a tie-breaking vote. The PPC will accept, reject, or ask for a resubmission with modifications for any manuscript proposal, and will inform the WG Chairperson of their decision and rationale for the decision. Requested modifications may relate to scope of work or WG membership.

PPC Step 5. Upon approval by the PPC, the manuscript proposal shall be given a manuscript number and this information, along with a description of the proposed paper, will be entered in the DCC's Manuscript Tracking Database, and the agreed upon timeline will be initiated. Information about the proposal will be posted to the private PPC website so that other Consortium investigators will be aware of projects that are in process.

9.0 Responsibilities of Manuscript Writing Group Members and Chairperson

WG Chairperson. The WG Chairperson, with assistance by the Co-chairperson, is responsible for all phases of manuscript preparation, from conception through publication. Responsibilities include:

- Preparation of the publication proposal.
- Distribution to all Teen-LABS site PIs for solicitation of co-authors.
- Coordination and communication within the writing group.
- Preparation of manuscript outline.
- Identification of data analyses needed from the DCC.
- Authority and responsibility to set interim deadlines for WG members to encourage progress

and completion of work. Deadlines will be made in consultation with the WG members and with the DCC (especially as it relates to completion of the various steps of data analysis). The WG Chairperson will communicate directly with the PPC Chairperson if difficulties arise in meeting interim deadlines to the extent that timely completion of the work is at risk.

- Preparation of interim status reports and their submission to the PPC.
- Assignment of tasks to Writing Group members, *specification* of clear deadlines for completion of these tasks, and ascertainment that the tasks are completed on schedule.
- Confirmation submitted to the PPC Chairperson and DCC that the manuscript has approval of the WG before submission of its Penultimate Draft to the PPC.
- Measure effort and contribution of WG members.
- Determination of the order of authorship on the manuscript. A major criterion for this determination shall be the effort and contribution made by the members of the WG in preparation of the manuscript. Disagreements regarding author order will follow the Conflict Resolution process.
- Recommendation of a journal to which the manuscript should be submitted. Selection of the journal for submission of the manuscript is delegated to the WG, with input from the PPC.
- Correspondence with co-authors, communication with the DCC and the PPC, and to journal editors.
- Respond to letters to the editor and related correspondence following publication of a manuscript. To the extent that reviewers or editors request additional information that goes beyond the scope of the original publication proposal, the WG Chairperson will complete a second proposal to request additional data and the PPC Chairperson will consider this request and decide whether further review by the PPC is necessary.

A Study investigator can serve as WG Chairperson for numerous active manuscript proposals, provided the investigator is productive, and timely with the workload. If the WG Chairperson submits a manuscript proposal to PPC and has not made considerable progress on other WG projects for which he or she is responsible, the newly submitted proposal may be tabled by the PPC, and the WG Chairperson will be encouraged to complete the manuscripts from their outstanding proposals.

WG Co-chairperson. The WG Co-chairperson functions to facilitate progress, conduct meetings or calls in the event of necessary absence of the WG Chairperson, and to assist the Chairperson in all aspects of the process. In the event that the WG Chairperson is an investigator not directly in the Consortium or is a student, resident, fellow, or post-doctoral scientist who reports to a Consortium Investigator, a Consortium Investigator will serve as the Co-chairperson. Co-chairpersons may be identified either by the WG Chairperson or by PPC and must be approved by PPC. Exceptions and changes to the assignment of a Co-chairperson can be made with approval of the PPC.

Members of the WG. Members of the WG are responsible for performance of tasks assigned by the WG Chairperson within the allotted time period. Each member is expected to actively participate in the preparation of the manuscript. While the WG Chairperson has the responsibility to respond to editorial comments and suggestions during the review process and make reasonable

changes to assure publication of the paper, this is in consultation with the Co-chairperson and WG members.

If a WG member does not accomplish the tasks assigned to him/her and has not contributed to the manuscript, he/she can be removed from the WG. WG Chairpersons will have the authority to measure the effort of the other WG members' contributions and remove non-contributing members from WG membership, and thus from the final listing of contributing authors. If the WG Chairperson wishes to remove a WG member, this process should begin with a discussion between the WG Chairperson and the WG member. If the issue cannot be resolved in this manner, the site PI overseeing the person to be removed will be contacted by the WG Chairperson. If resolution is not achieved or if the person to be removed is the site PI, the Chairperson of PPC is to be informed, and the Chairperson will proceed with steps towards conflict resolution as outlined in this document.

10.0 Specific Roles and Responsibilities of PPC and Liaisons to Monitor and Facilitate Progress in Manuscripts

10.1 Specific Responsibilities of the Liaison in monitoring progress

The liaison is a member of the PPC who has the authority and responsibility to monitor progress on specific papers assigned to her/him and to encourage progress. If there are concerns regarding progress on a specific paper, the liaison will communicate directly with WG Chairperson, and, if concerns persist, with PPC Chairperson. The liaison is delegated the authority to review and approve or disapprove abstract submissions that are developed from approved manuscript/abstract proposals. The liaison will update the PPC at the next scheduled conference call of any abstracts developed and their status. Should any conflict arise between the writing group Chairperson and the liaison concerning abstracts, these will be resolved by the PPC Chairperson. The liaison also will serve as the primary reviewer of the manuscript during PPC discussions. The liaison can become a member of the WG and co-author the publication that they have liaison responsibility for provided the liaison meets other authorship criteria described above.

10.2 Specific Responsibilities of the PPC in monitoring progress

The PPC has the authority and responsibility to:

- Monitor papers for progress over time, and to encourage progress, typically via the PPC member assigned as Liaison for the specific paper. This will be done in consultation as needed with the Steering Committee, and the writing group Chairpersons of specific papers, as well as the DCC for issues related to work load and efficiency. If there are concerns regarding progress, the PPC will communicate this directly to the WG Chairperson.
- Require limitations on the scope of work to reasonably reflect the original, approved proposal, should procedures outlined not result in a mutually agreeable scope of work in the manuscript.
- Request modifications to approved proposals. During the course of manuscript preparation or revision based on editorial review, it may become necessary to modify the scope of the analysis. The WG Chairperson should notify the PPC Chairperson in writing of proposed modifications and their rationale. The PPC Chairperson is delegated authority to determine if the proposed changes are acceptable or not and to inform the PPC in a timely manner. Issues that must be considered in this decision (among others) are: whether the proposed changes meet current study goals; whether significant overlap would occur with other approved manuscripts; whether data are available in a timely fashion given other priorities,

etc. If there is any concern on the part of either the writing group or PPC Chairpersons, the decision will be referred to the full PPC for review and decision.

- Modify Writing Groups. The PPC may propose to change the composition of the WGs, including the WG Chairperson, if the required manuscript has not been produced according to the originally agreed upon content and schedule. If the PPC is considering such an action, the PPC Chairperson will discuss this directly and privately with the WG Chairperson as a first step. If needed, the conflict resolution process will be followed. A formal proposal from PPC to remove or reassign the responsibility of WG members will be reviewed and decided by the Steering Committee.
- Enforce the “One proposal-one manuscript” policy. If the WG for an approved paper proposal determines that more than one paper will result from the original proposal, then new proposals need to be submitted for approval, with a note of explanation that indicates that the new proposals replace the original approved proposal. This will result in a “one proposal - one manuscript” policy. Note that it is possible for the original Chairperson will continue to Chairperson new and related proposals, but this is not assumed. Rather, for the more detailed papers that arise from the original proposal, different expertise may be required and this often will lead to slightly differently configured WGs than originally foreseen. The new proposals must be written using a similar process as the primary proposal.
- Enforce the Teen-LABS Honor System

11.0 Final Approval Process Prior to Submission of Manuscripts for External Review (or Abstracts that directly result from work on an Approved Manuscript proposal)

The WG Chairperson should submit a manuscript to the Teen-LABS PPC in the format suitable to submission to the targeted journal. After internal review and conditional approval by the Teen-LABS PPC, the manuscript will be forwarded to the LABS Steering Committee for approval. The LABS Steering Committee is requested to respond with a “Yes” or “No” vote within 1 calendar week. Non-response in this time period constitutes a “Yes” vote. In the case of a “Yes” vote, the LABS Steering Committee may opt to provide minor comments and edits to improve the quality of the paper. However, a “No” vote by the LABS Steering Committee will require that a written response be provided to the Teen-LABS Chairperson outlining the rationale for the rejection. In response to the latter, the Teen-LABS Chairperson will ask the WG Chairperson to write a rebuttal addressing the concerns of the LABS Steering Committee.

Note: For both papers and abstracts, NIH clearance is needed if an NIH investigator is a named author. NIH clearance is NOT needed for either papers or abstracts if NIH is not included in authorship. NIDDK investigators must be invited to participate as part of the writing group.

12.0 Submission of Manuscripts for Publication

The WG leadership will be responsible for the logistics of manuscript submission and associated communications. The PPC and DCC may provide advice and administrative support as deemed necessary during this process. The WG Chairperson will respond to reviewer comments, and review/edit publication galleys. The WG Chairperson should provide a copy of the final submitted abstract and manuscript to the Teen-LABS PPC.

13.0 Submission Process of Abstracts and Presentations

All abstracts require proposal submission and approval, and should adhere to all policies and procedures as previously described. It is understood that, due to abstract and presentation deadlines, flexibility in implementing this process may be required.

The WG for each abstract proposal will be responsible for preparing a full manuscript in advance of the scientific meeting. The WG chairperson will identify a timeline for completion of the analyses and abstract preparation, and subsequent writing of the manuscript.

The PPC strongly discourages submission of abstracts to more than one meeting, unless special circumstances permit. The PPC must ensure that the same abstract is not published more than once.

The WG Chairperson will provide reasonable time for members of the WG to comment on the material to be presented. Slides, tables, and/or a presentation script must be sent to the PPC Chairperson (or designee) at least 2 weeks or a mutually agreed timeframe prior to the scheduled presentation for review and approval.

The WG Chairperson is encouraged to plan a timeline for manuscript completion after abstract submission that yields a finished product well before the date of the meeting. This will ensure that the analyses to be presented at the meeting have been thoughtfully reviewed by the WG and will facilitate more rapid publication of study results after presentation.

The actual live presentation of the material must be done preferably by the WG Chairperson, but can be done by another co-author as his/her designee. The material communicated during the live presentation must conform to the content approved by the WG and PPC Chairperson. Deviation from approved content (e.g., methods, results, conclusion, and interpretation) is not allowed as it could challenge the academic integrity of the Consortium.

In the event that a paper is published in advance of the scientific meeting, the guidelines for the meeting should be reviewed to determine if the abstract needs to be withdrawn.

Official Teen-LABS logos and NIH logos will be used on all presentations, as permitted by conference organizers. Site-specific logos are not to be used on posters and presentations that include study-wide data. Use of these logos is appropriate for local presentations that include site-specific data.

Funding source will be cited for all abstracts/presentations/manuscripts.

14.0 Procedures for Press Releases

In general, press releases about study findings will be prepared by the WG Chairperson of the individual paper or designee and reviewed by the PPC prior to submission to the Steering Committee for final review prior to release. These press releases should be given to the media when interviews are requested to help ensure uniformity and accuracy in the information disseminated through the media. Press releases must be approved by the Teens-LABS PPC and Steering Committee before issue. Any press release issued by the NIDDK should be reviewed by the PPC and the Steering Committee prior to its release. Press releases based on papers pending publication must contain accurate information about the time when the embargo will be lifted as

stipulated by the journal publishing the paper. In the case where more than one center is issuing a press release about a specific paper, the WG Chairperson should be made aware and coordinate these press releases.

15.0 Procedures for Letters to the Editor and Responses to a Journal Letter Based on a Teen-LABS or Non-Teen-LABS Manuscript

Letters to the Editor are a common way for ideas to be exchanged. In some cases, the Letter format may be an appropriate place for information learned from Teen-LABS to be presented, rather than in a full manuscript. Also, Teen-LABS investigators may be invited to respond to a Letter received by the journal written in response to a Teen-LABS manuscript. These Letters are reviewed by the Editor and, in most cases, author disclosures are required. There is generally a very quick turnaround time for these letters to be received and published.

Letters responding to a journal letter based on a Teen-LABS manuscript should be submitted to the PPC Chairperson for approval. Letters written on behalf of the Teen-LABS consortium in response to a non-Teen-LABS manuscript also should be approved by the Teen-LABS Study Chairperson and PPC Chairperson. Any letter which includes previously unpublished Teen-LABS data must be approved by the PPC and by the Steering Committee as if it were a regular publication. If there is a quick turnaround time for the submission of this Letter, approval may be obtained by e-mail.

16.0 Procedures for Media Interviews

To facilitate the dissemination of information to the public concerning the Teen-LABS study, while maintaining uniformity, accuracy, and scientific integrity of the Teen-LABS Consortium, members of the Steering Committee are authorized to discuss the purpose and objectives, methods, and published or presented data, with local media. Where media deadlines allow, written submission of questions and the investigator's responses should be submitted to the PPC Chairperson for review and approval. When this is not possible, Steering Committee members are allowed to answer local media inquiries. The Steering Committee member or their designee is responsible for notifying the PPC Chairperson that an interview took place and with whom. When possible, a copy of any printed article should be sent to the DCC for distribution to the Consortium members and archiving.

Because national publicity has potential to adversely affect the reputation of the Teen-LABS study, questions by national media should be directed to the Teen- LABS Principle Investigator. National media includes network television, network radio, major newspapers, national newsletters, widely disseminated university publication, and major news websites. When appropriate, the Teen- LABS Principle Investigator will notify and seek consultation from the PPC Chairperson and cooperating federal agencies. The Teen-LABS Principle Investigator may delegate a steering committee member or other qualified expert to answer national media questions.

17.0 Procedures for Teen-LABS Conflict Resolution

It is the intent of the stated Publications and Presentations policies to ensure efficient and fair procedures for maximizing the scientific productivity of Teen-LABS. In particular, these policies are designed to avoid conflict in the areas of authorship and scientific overlap across publications and presentations.

It is recognized that conflict may arise regarding Teen-LABS publications or presentations. Should conflict arise that cannot be resolved by the interested parties themselves, this will be brought to the attention of the Study Chairperson or Chairperson of the PPC, who will determine the first step towards conflict resolution. In many cases, resolution will occur via facilitated discussions among the parties concerned. As needed, the issue will be brought before the PPC for discussion and recommendations for resolution, relative to the stated PPC goals and policies. If resolution is not achieved to the satisfaction of the parties, then the issue will be brought before the Steering Committee. In all cases, values of fairness and respect will be upheld.

18.0 Publication cycle – A Summary

- a. Topic defined by or approved by PPC (when applicable).
- b. WG Chairperson and Co-chairperson determined by Study Chairperson and Co-Chairperson in collaboration with the PPC Chairperson for Key Papers. WG Chairperson and Co-chairperson “self-identify” in the case of all other publications initiated by Consortium investigators).
- c. Manuscript proposal written by WG Chairperson and Co-Chairperson and 1 - 2 other Consortium members, including DCC analyst or statistician.
- d. Manuscript proposal distributed to all Teen-LABS PIs by WG chairperson for solicitation of additional WG members (co-authors).
- e. Review and approval of manuscript proposal by the PPC. Submit publication concept sheet to LABS P & P committee.
- f. Notification of WG Chairperson of PPC decision – Tracking database populated and timeline is initiated, proposal posted to study website.
- g. Modifications to proposal by WG committee, if necessary.
- h. Submission of a draft manuscript to the PPC in the format of the targeted journal.
- i. Modification to manuscript by WG committee based on the PPC meeting, if necessary.
- j. PPC to verify that all relevant funding source(s) (e.g., Teen-LABS grant number, LABS grant number [if relevant to the project], and any other source) for the study are appropriately acknowledged.
- k. Submission of completed manuscript to LABS P & P committee for approval.
- l. Submission of completed manuscript to designated journal after final Teen-LABS PPC approval.
- m. Communication beyond this point on the status of the manuscript will occur between the PPC and the WG Chairperson, who will communicate with WG members.

19.0 Timeline of a Manuscript – A Summary

A draft manuscript must be submitted to the Teen-LABS PPC Chairperson no later than 3 months after approval of the proposal and at least 10 working days prior to review at a regularly scheduled PPC meeting. Revisions must occur within 2 months of receiving PPC comments. If revisions are deemed minor, a revised manuscript must be resubmitted to the PPC Chairperson at least 10 working days prior to the next scheduled PPC meeting. *All Teen-LABS authors are advised that publications also must conform to LABS PPC guidelines and policies.* Prior to final approval, the Teen-LABS PPC Chairperson will forward the manuscript to the LABS Steering Committee for review and publication authorization. A manuscript or article is expected to be submitted for publication within 1 month of receiving final notification of approval from the Teen-LABS PPC Chairperson.

It is anticipated that the majority of papers will take on average 4-6 months to be submitted to a Journal for publication from the time of proposal initiation, although a shorter timeline is encouraged. It is expected that no more than 6 weeks should elapse from the time of notification of a paper being rejected (or in need of revision) before it is resubmitted unless extensive re-analysis or the addition of additional cohort years is required. The WG Chairperson should communicate with the lead biostatistician in a timely manner if additional analyses are required for resubmission. In cases where journals request a shorter turn around time for revisions (30 days), the journal timeline supersedes the 6-week expectation of PPC.

The goal of these timelines is to enhance productivity. If unforeseen circumstances occur that prevent a WG from adhering to the timeline, the WG Chairperson should contact the Teen-LABS PPC Chairperson to inform the PPC of the circumstances and request a revised timeline. The PPC may intervene by suggesting possible changes in WG Chairperson or WG composition if there is a significant lapse in productivity in completing and submitting a manuscript for publication.

See Appendix for forms and further details regarding timelines for the publication process.

20.0 The NIH Public Access Policy

The NIH Public Access Policy implements Division G, Title II, Section 218 of PL 110-161 (Consolidated Appropriations Act, 2008) which states: *SEC. 218. The Director of the National Institutes of Health shall require that all investigators funded by the NIH submit or have submitted for them to the National Library of Medicine's PubMed Central an electronic version of their final, peer-reviewed manuscripts upon acceptance for publication, to be made publicly available no later than 12 months after the official date of publication: Provided, That the NIH shall implement the public access policy in a manner consistent with copyright law.*

- The online link to this policy and procedure for submission of NIH funded work (NIH Guide Notice NOT-OD-08-033) can be found at:
<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-033.html>.
- It will be the responsibility of the WG Chairperson to follow the NIH policy on manuscript submission as indicated in the link above.
- It will be the responsibility of the Teen-LABS PPC Chairperson to verify that the NIH Public Access Policy has been followed for each peer-reviewed manuscript produced by the Teen-LABS Consortium.

21.0 DCC Data Request Policy and Timelines

Individuals requesting information from the Teen-LABS database should review the Teen-LABS Data Request Guidelines. Please note, **the Teen-LABS DCC will require at least “6 weeks” from approval to fulfill the data requests.** In situations where additional time is needed to fulfill the request, the DCC will provide an estimate of the required time necessary to complete the data request.

Acknowledgments

In drafting the present Teen-LABS Consortium Publications and Presentations Guidelines we had the benefit of referring to the Publications Guidelines from the LABS Consortium, who in turn acknowledged their use of 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. Additional sources of reference made available to Teen-LABS were the Publications, Presentations, and Ancillary Studies guidelines from the SEARCH for Diabetes in Youth Study.