

Updated: February 2013

Attachment 5: REDS-III Publication Manual
OMB Number: 0925-XXXX

RECIPIENT EPIDEMIOLOGY AND DONOR EVALUATION STUDY-III
(REDS-III)

PUBLICATIONS COMMITTEE POLICY MANUAL

January 2012

(Revised February 2013)

Prepared by:

REDS-III Coordinating Center
RTI International

Updated: February 2013

Sponsored by:

National Heart, Lung and Blood Institute
National Institutes of Health

I. INTRODUCTION

A major responsibility of the REDS-III program is to disseminate research findings through scientific publications and presentations. The mission of the Publications Committee is to ensure that the REDS-III program contributes substantially to the science of blood safety and availability, and transfusion medicine practice. To accomplish this mission, the Publications Committee, in conjunction with NHLBI, prioritizes analyses and publications to maximize the scientific impact and public health contribution of the REDS-III program. The Committee also serves as a facilitator for disseminating REDS-III study findings and provides a mechanism for in-program peer review of publications and presentations.

Investigators are encouraged to submit analysis requests, including meeting abstracts, with the intent of publishing the results in a fully developed manuscript in a peer reviewed journal. Any abstract, presentation, and/or publication including and/or presenting REDS-III data (defined as any data collected by the REDS-III program) needs to be reviewed and approved by the REDS-III Publications Committee, as well as reviewed by NHLBI before the abstract and publication can be submitted to a Journal, or before a presentation is given. Any investigator (regardless of his/her Institutional affiliation with the REDS-III program) developing an abstract, presentation, or publication as a result of his/her participation in a REDS-III study or in analyses of data collected for the REDS-III program is required to abide by this policy. The policy applies whether the abstract, presentation, or publication is in English or another language.

Specifically, the Publications Committee is charged with: 1) reviewing the analysis requests, presentations and publications that use data obtained by the REDS-III program, 2) approving (usually by consensus) the analysis requests, presentations and publications that will be developed by the REDS-III program, 3) prioritizing the approved analysis requests, presentations and publications as necessary, 4) ensuring that the data presented are of the highest quality possible and that the interpretation and conclusions reached are supported by the data, and 5) facilitating optimal utilization of the datasets, and presentation and publication opportunities, for all REDS-III investigators.

Although direct access to REDS-III data by investigators will be limited in accordance with the contract requirements for FIPS moderate level security at the DCC, the DCC will provide each site with an analyzable copy of its own data from the cumulative donor/recipient database on a regular basis for operational purposes.

II. ORGANIZATION OF PUBLICATIONS COMMITTEE

There will be a single Publications Committee for the domestic and the international components of REDS-III. Membership is open to all interested participants; however, each contracted institution will have only one vote. Table 1 lists the voting members of the committee. The alternate voting member will be allowed to vote when the voting member is unable to participate. Other REDS-III investigators are welcome to attend meetings, propose and lead manuscript development, but cannot vote.

The Publications Committee Chair is designated by Executive Committee and will be responsible for committee correspondence and meetings, and for timely communication with the Writing Groups. The Data Coordinating Center (DCC) will assist the chairs of the committee in executing these responsibilities. A Publications Coordinator will be assigned by the DCC and supervised by Ms. Sullivan.

Table 1. REDS-III Publications Committee (PC) Voting Membership

Alternate Voting Member	Voting Member	Institution
	Dr. Roger Dodd	Publications Committee Chair
	Dr. Steven Kleinman	Oversight Steering Committee Chair
Dr. Eberhard Fiebig	Dr. Edward Murphy	University of CA San Francisco
Dr. Joseph Kiss	Dr. Darrell Triulzi	Institute for Transfusion Medicine
Dr. Jerry Gottschall	Dr. Alan Mast	BloodCenter of Wisconsin
Mr. Bryan Spencer	Dr. Edward Snyder	Yale/American Red Cross
Dr. Jing Xing Wang	Dr. Hua Shan	Johns Hopkins University/China
Dr. Ester Sabino	Dr. Brian Custer	BSRI/Brazil
Dr. Robert Crookes	Dr. Evan Bloch	UCSF/South Africa
Dr. Shimian Zou	Dr. Simone Glynn	NHLBI
Ms. Marian Sullivan	Dr. Don Brambilla	RTI
Dr. Philip Norris	Dr. Michael Busch	Blood Systems Research Institute

III. ROLE OF THE DATA COORDINATING CENTER

RTI is committed to efficiently and effectively coordinating and supporting all analytic activities and the development of scientific publications and manuscripts for REDS-III. DCC staff, particularly the analysts and biostatisticians, will work closely with the REDS-III investigators in refining data analysis requests; submitting the requests to the Publications Committee for review; providing programming and analytic support; and supporting the development of publications and presentations. The Publications Coordinator will assist the Chair of the

Publications Committee and serve as the conduit for receiving, distributing, and channeling analysis requests and manuscripts through the committee.

For each approved analysis, the submitting investigator who is typically the Writing Group Chair and first author of the resulting manuscript and the associated Writing Group will be assigned a lead analyst at RTI. The analyst will assist in setting up conference calls and agendas for relevant discussions; provide the Writing Group with specified output (e.g. frequency tables, cross tabulations, results of statistical tests and models, etc.) for review; draft portions of the “Methods” and “Results” sections for manuscripts as requested; and assist with responding to comments received from the journal subsequent to submission of the manuscript. In general, the DCC will use standard statistical and graphics packages (e.g., SAS) for all analyses.

IV. PROCEDURES FOR DATA ANALYSIS REQUESTS AND MANUSCRIPT DEVELOPMENT

Investigators are encouraged to submit analysis requests, including meeting abstracts, with the intent of publishing the results in a fully developed manuscript in a peer reviewed journal. Analysis proposals may be initiated by REDS-III investigators or other interested persons outside of REDS-III. Requests from non-REDS-III investigators must be sponsored by a REDS-III investigator. Investigators are expected to include DCC analysts and other staff with specific expertise (e.g. epidemiology, genetics) in planning discussions.

Analysis requests received from non-REDS-III organizations or other government offices will be directed to the NHLBI REDS-III COR. The COR must provide approval before an analysis request can be referred to the Publications Committee.

Analysis requests should be submitted to the DCC using the template shown in Attachment A (***REDS-III Research Data Analysis Request Form***) and the guidance provided below. The analysis request should include as much detail as possible to facilitate review of the request and assessment of the required resources.

The Publications Committee will judge each proposed analysis request on its scientific merit and contribution to the field of blood safety and availability. If approved, a Writing Group of interested collaborators will be formed and analysis will begin. The resulting abstract, presentation, and manuscript should in turn be submitted to the Publications Committee for review. All REDS-III abstracts/presentations and publications need to be approved by the Publications Committee (a consensus is required) and reviewed by the NHLBI REDS-III COR before submission to a conference for presentation or to a journal.

1. Content of an Analysis Request Submission

The analysis request should be submitted via the REDS-III private website to the Publications Coordinator, who will forward it to the committee for review. Requests that refer to an analysis that is already part of a specific study protocol can simply refer to the statistical section of the protocol. The *REDS-III Research Data Analysis Request Form* (Attachment A) includes the following sections:

- A brief description of the analysis, including a statement of its content, focus, hypothesis to be tested (if any) and background;
- A definition of subjects or specimens eligible for inclusion, e.g., all blood donors, or donors with a given condition or laboratory test, or some other subset of donors, recipients, or specimens;
- A list of study variables of interest and the source for these data points, (e.g., on what forms they are contained);
- A list of possible co-authors and collaborators who will comprise the Writing Group;
- If a presentation or abstract is planned, the submission should include the name and date of the meeting or conference, and a timetable for the analysis.

2. Publications Committee Review of Request

The initial analysis request will be circulated by the Publications Coordinator to the members of the Publications Committee at least four days before the scheduled conference call. If a proposal is received later than four days before the call, it will be reviewed during the next conference call.

Publications Committee members will review the requests based on the scientific impact and public health contribution of the resulting publication or presentation to the fields of blood safety and availability, and transfusion medicine. Additionally, the committee will consider the requests:

- Data needs, to ensure availability of the appropriate data in REDS-III to address the hypothesis or aims of the proposal;
- Scope, to ensure that it is reasonable and feasible; and
- Timetable, to ensure that it is consistent with other REDS-III priorities.

If the Publications Committee feels that there is substantial content overlap between a new request and either an existing one or another new one, the chair of the Publications Committee will organize a conference call with the two investigators, and appropriate analytic representatives from the DCC to refine the content areas of the two requests to eliminate the overlap. The revised request(s) should then be resubmitted to the Publications Committee for review.

In the absence of consensus, Publications Committee voting members will be asked to score approved proposals on a scale from 1 to 5, with one being the highest score for scientific merit and contribution. In general, high scores will be given to requests stemming from ongoing protocols, given that these protocols were approved for conduct based on the scientific merit of the research. A high score for an analysis request generally indicates that it will lead to a manuscript or presentation that should be released as soon as possible. A medium priority score is given when the Publications Committee feels the topic is of interest to a large segment of the research community, but is not time sensitive. A low priority score reflects a topic that is of interest to a limited segment of the research community and is not time critical.

The Committee's goal is to communicate decisions to the Writing Groups within one week of the review meeting/call. The Chair of the Publications Committee, with assistance from the Publications Coordinator, is responsible for notifying the Writing Group investigators of the outcome of the review by email. Once approved and scored, the DCC will work on each request as prioritized by the committee. To this end, an analyst and biostatistician from the DCC will be charged with working with the investigator to develop, if needed, a more complete analysis plan. This will ensure that all critical and specific details are identified at the outset. More information on this is provided in Section 4.

3. Formation of a Writing Group and Authorship on Publications

Upon approval of an analysis request, the submitting investigator will determine whether any other REDS-III investigator(s)/collaborator(s) are interested in participating as part of the Writing Group. In most cases, the investigator initiating the analysis request will serve as the Chair of the Writing Group and as the first (or last) author. REDS-III investigators may also include non-REDS-III investigators as members of the Writing Group, as appropriate. REDS-III investigators are responsible for letting the Writing Group Chair know of their interest in actively participating in the drafting of the manuscript within two weeks after an initial submission is approved.

Once the Writing Group is formed, the first responsibility of the submitting investigator is to determine authorship, in conjunction with his/her Writing Group. REDS-III Writing Groups will adhere to the following guidelines for determining authorship based on the standards of the International Committee of Medical Journal Editors at <http://www.icmje.org/#author> :

- In general, authorship should be restricted to those individuals who have met each of three criteria: (a) made significant contribution to the conception and design, or acquisition of data, or the analysis and interpretation of data or other scholarly effort, (b) participated in drafting the article or reviewing and/or revising it for important intellectual content, and (c) approved the final version of the manuscript to be published. Conditions (a), (b), and (c) must all be met.
- In our case, the submitting investigator (who is usually the Writing Group Chair and the first author) has the responsibility for: (a) including as co-authors all those who meet the three criteria defined in Part 1 of this Policy and excluding those who do not; and (b) obtaining from all co-authors their agreement to be designated as such, as well as their approval of the final version of the manuscript, and a completed Authorship Form. Of course, any person can refuse to be a co-author if they elect to do so.
- Co-authors assume full responsibility for all work submitted under their names and, as a co-author, acknowledge that they meet each of the three criteria for authorship as defined in above.

It is also the responsibility of the Writing Group Chair to move the analysis and writing along as quickly as is consistent with the production of high quality work, to involve all group members in the process as much as possible, and to adhere to the timetable for the manuscript described in the analysis request. The Writing Group Chair will circulate drafts to Writing Group members for their review and input prior to submission to the Publications Committee.

If the Publications Committee determines that a Writing Group is not proceeding satisfactorily toward a final product, the Publications Committee Chair will first attempt to resolve the problem working directly with the Writing Group Chair. If unsuccessful, the Publications Committee Chair will contact the Steering Committee Chair and the NHLBI REDS-III COR.

4. Content of Detailed Analysis Plan

After determining authorship, the DCC is responsible for working with the Writing Group (in particular, the Chair) to develop a detailed analysis plan and timetable. The detailed analysis plan does not need to be reviewed by the Publications Committee. Considerable time can be saved by creating thorough analysis plans that minimize revisions once the analysis is launched. The analysis plan needs to contain the following elements.

- Datasets to be used.
- Data variables to be used; for computed variables, documentation on the composition of the variables should be included.
- Presentation of the basic analysis/statistical approach, i.e., preliminary analysis, univariate analysis, multivariate analysis, advanced analytic approaches.
- Indication of the graphic and table needs for the final manuscript, (i.e., does the Writing Group want to include a number of graphics to illustrate some of the points, or only tables).
- Indication of the target audience of the journal.
- Proposed timetable for each stage. This will be developed by the Writing Group Chair in coordination with the DCC.

5. Preparation and Submission of Manuscripts

Once the analysis has been conducted and the Writing Group has drafted the manuscript, the Writing Group Chair should forward the manuscript electronically to the Publications Coordinator at the DCC (TBD). Included in the submission should be an indication of the target journal.

6. Review and Approval of Manuscripts

Publications Committee Review: English-Language Manuscripts

Manuscripts for review should be submitted to the Publications Coordinator at the DCC at least one week prior to the Publications Committee meeting to allow for a meaningful review. In general, only the REDS-III Publications Committee members will review manuscripts. However, the Publications Committee may include others as needed for manuscripts which require specialized

expertise. Each manuscript will be reviewed to ensure that the:

- Title is descriptive and appropriate.
- Abstract captures important information of the article.
- Introduction and literature review are current and provide the back ground necessary for the central hypothesis.
- Central hypothesis is stated explicitly and answered by the analysis presented.
- Materials and Methods section is complete or refers to previous publications as appropriate.
- Results section includes all appropriate analyses to support the discussion section.
- Tables and graphs (if any) are appropriate and well-constructed and should convey the intended information.
- Discussion is appropriate for the analysis and answers the central hypothesis.
- Conclusion or summary section is succinct and adequately summarizes the findings.
- The Coordinating Center has verified all numbers and statistics in the manuscript.

Publications Committee Review: Chinese-Language Manuscripts

There is a two-step process for approval of papers written in Chinese for Chinese journals. First, the Writing Group Chair must submit the full article in Chinese to the US Principal Investigator (PI) of the REDS-III China Program (Dr. Hua Shan; hshan@jhmi.edu). It will be evaluated according to the bulleted criteria above by an Initial Review Group including the US PI for China, an NHLBI representative designated by the REDS-III COR, a team member of the China Program designated by the US PI, and the RTI coordinator for the China Program,. That group may approve the manuscript, request revisions, or reject the manuscript.

After the full article is approved by the Initial Review Group, the investigators must submit an English translation of the major data tables to the Publications Committee Coordinator at the DCC (TBD). The Coordinator will arrange a teleconference between the Writing Group Chair, the Initial Review Group, and a Publication Committee subcommittee that includes the Oversight Steering

Committee Chair, the Publications Committee Chair, and the NHLBI REDS-III COR. The Writing Group Chair will give an oral summary of the data and discuss its interpretation with the subcommittee. The Chair of the Publications Committee, with assistance from the Publications Coordinator, will notify the Writing Group Chair of the outcome of the review by e-mail.

NHLBI Review

Every abstract, presentation, and manuscript must be reviewed by NHLBI before submission and/or presentation. The final manuscript as approved by the Publications Committee will be submitted to the NHLBI REDS-III COR for review. (For Chinese-language manuscripts, NHLBI will receive an English translation as well as the Chinese version.) Contract provisions must be followed. Following review by NHLBI, the first author may submit the final manuscript to the journal.

7. Procedures for Manuscript Revision

If a manuscript is returned by a journal for revision, the Writing Group should undertake those revisions as soon as possible. If additional analyses are required, they will be given high priority at the DCC. The revised manuscript, along with a letter or memo describing the revisions, should be submitted to the journal by the first author.

8. Review of Galley Proofs

The review of galley proofs is the responsibility of the first author. If he/she is unable to review the proofs by the specified deadline, another author should be appointed to perform this task.

V. PROCEDURES FOR ABSTRACTS AND PRESENTATIONS

1. Abstracts and Associated Presentations

There are multiple steps involved in the Publications Committee abstract approval process: approval of the abstract idea (through the submission of an analysis request), approval of the abstract text, and final approval of the actual presentation, which could either be PowerPoint slides for an oral presentation or a poster presentation. The investigator must submit the proposed abstract concept to the Publications Committee—this may follow from a previously approved analysis request or it may be part of a new analysis request. Once approved, the Writing Group investigator(s) will develop a draft abstract for review by the Publications Committee at a minimum of one week and, optimally, two to three weeks prior to the abstract submission deadline. After review by the Publications Committee, the primary author will edit the abstract based on

Publications Committee feedback. A second review of the edited abstract may be conducted (either by e-mail or by phone) at the discretion of the Publications Committee. Once approved, the final draft of the abstract can be submitted by the primary author; a copy of the final abstract should be submitted to the DCC Publications Coordinator.

If accepted, the draft presentation (oral or poster) will be reviewed by the Publications Committee prior to its public presentation.

2. Invited Presentations

REDS-III investigators may be invited to make presentations at various meetings and other venues, including less formal presentations within their own institutions, where an abstract submission is not required. In such cases, approval from the Publications Committee is needed prior to an investigator accepting the invitation. When a personal invitation to a REDS-III investigator to make a presentation is received, the investigator should notify the Publications Committee Chair. In some cases, a presentation may require the DCC to analyze data, which will require the submission of a data analysis request. Authors should include the presenter plus any other investigators who worked on the presentation on behalf of REDS-III.

It is required that the draft presentation be reviewed by the Publications Committee prior to its public presentation. The Publications Committee Chair, with the agreement of the REDS-III COR, may waive this review if the content of the presentation is similar to previous REDS-III presentations on the same topic.

3. Preparation and Submission of Presentations to the Publications Committee

Presentations should be prepared at the investigator's institution unless resources are not available, in which case, the DCC may provide assistance. After preparation, the presentation should be electronically submitted to the DCC for circulation to the members of the Publications Committee.

A standardized REDS-III slide template will be developed by the DCC for the use of the presenters if they so choose. This will be available on the internal REDS-III website in the Publications Committee area. Regardless of whether the slide template is used, presenters *must* adhere to the following instructions for slides and posters:

- The official REDS-III logo, also available on the website, must be displayed.
- Institutional logos should *not* be displayed.
- The NHLBI logo should not be displayed unless it is an official NHLBI presentation.

Manuscripts and abstracts *must* include the following statement in the masthead “For the NHLBI Recipient Epidemiology and Donor Evaluation Study-III (REDS-III)”.

4. Criteria for Review and Approval of Abstracts and Presentations

In general, only the REDS-III Publications Committee members will review abstracts and presentations but may solicit additional specialized expertise as needed. Each presentation will be judged by the Publications Committee for approval in the following areas:

- The material is appropriate for illustrating the major points in the abstract.
- Appropriate background material is presented.
- The Coordinating Center has verified all numbers and statistics in the abstract and presentation.
- The quality of the material preparation is acceptable.
- The conclusion or summary is appropriate for the data presented.

5. Chinese-Language Abstracts and Presentations

Review of abstracts and presentations in Chinese will follow the procedure outlined above for manuscript review.

6. Reprints

All requests for reprints are to be directed to the REDS-III DCC or to the first author, if he/she desires. The DCC will keep a list as well as an archive of all study publications.

7. Adjudication of Writing Group Disputes

The Writing Group will take unresolvable disputes to the Publications Committee Chair, who will resolve the problem with the help of the Committee and NHLBI if needed.

8. Abstracts, Presentations, and Manuscripts Archive

All investigators will be asked to provide the DCC with final electronic copies of their abstracts, presentations, and manuscripts. The DCC will maintain an inventory of all publications and presentations and these will be posted on the REDS-III website. Reprints of journal articles will be circulated to all relevant Steering Committees and to the Publications Committee and NHLBI on a periodic basis.

**REDS-III
RESEARCH DATA ANALYSIS REQUEST FORM**

THIS FORM MUST BE USED FOR ALL REQUESTS FOR REDS-III DATA SUMMARIES AND/OR ANALYSES. COMMITTEE APPROVAL IS REQUIRED BEFORE WORK CAN BEGIN.

Date of Request: month/day/year

Individual Initiating Request:

Institution:

Telephone #:

E-mail:

If non-REDS-III investigator is initiating request, key REDS-III investigator involved:

Project Title:

Summary Description:

I. Hypothesis being examined:

II. Outline of analysis plan (Attach additional sheets if necessary):

III. Methods

1. Detailed definition of characteristics of dataset to be analyzed (i.e., time period, blood center, age, sex, race, donation type, etc.)
2. Analyses to be performed on data. Include summary table formats and statistical tests requested, if known.

IV. Reporting Results

1. Format in which statistical results are to be provided to investigator (e.g., hard copy or electronic media)
2. Date when results are needed by investigator.
3. Date when results (including all data tables) will be submitted for Publications Committee review (must be at least 3 weeks prior to planned presentation).
4. Proposed data use and forum for data presentation:

Meeting	
Date	
Location	
Published Report	
Journal	

5. REDS-III investigators should propose a list of possible co-authors and collaborators.

I UNDERSTAND THAT ANY PRESENTATIONS USING REDS-III DATA WILL ACKNOWLEDGE THE SUPPORT OF THE RECIPIENT EPIDEMIOLOGY AND DONOR EVALUATION STUDY-III AND THE NHLBI CONTRACT. ALL PRESENTATIONS, SLIDES, AND/OR MANUSCRIPTS MUST BE SUBMITTED TO THE REDS-III PUBLICATIONS COMMITTEE FOR REVIEW AND APPROVAL PRIOR TO PRESENTATION OR SUBMISSION FOR PUBLICATION.

Signature: _____
(Individual Initiating Request)

Date: _____

Signature: _____
(REDS-III Key Investigator as needed)

Date: _____

FOR RTI USE ONLY:

Received: ___ ___ ___

Concept approved: YES NO DATE: ___ ___ ___

Final analysis approved: YES NO DATE: ___ ___ ___